ANNEX B

Date: 24/10/2011

STANDARD FORMAT FOR TERMS OF REFERENCE (TOR)

Full title: Impact in the EU and third countries of measures on animal cloning for food production in the EU.

Lead Official/s & Unit [redacted] and [redacted] Unit E6

DG Co-chef de file

(Refer also to unit 02 and unit 01) [redacted] Unit O2

1. PURPOSE OF THE CONTRACT

IA study/ex-ante evaluation.

1.1 Context of the study work

In January 2008, the Commission tabled a legislative proposal for the revision of Novel Food Regulation (EC) n° 258/97 to streamline the authorisation procedure while maintaining the principle of a pre market approval for novel foods. The use of the cloning technique as such emerged in the inter-institutional discussions on this proposal. At first and second EP reading, all the Member States in Council were in favour of the inclusion of food from the offspring of clones (1st generation) in the Novel Food scope while the Commission was of the opinion that it should only cover food from clones as it is the case under current regime.

Following its Resolution of January 2008 on cloning, the European Parliament was against the principle of a possible authorisation of food from clones and their offspring under the Novel Food Regulation. The EP was in favour of a total ban of the use of the cloning technique in the EU and the placing on the market of food from clones themselves and their offspring (first and subsequent generations).

In view of a final agreement on the Novel Food revision, the Commission adopted in October 2010 a report to the EP and the Council on animal cloning for food production which suggested a number of possible measures on cloning:
(i) temporary suspension of the use of the cloning technique in the EU for the reproduction of all food producing animals; the use of clones for food production; the import of clones and the marketing of food from clones.
(ii) Setting up of a mandatory traceability system for the imports of semen and embryos from clones to allow farmers and industry to set up data bank(s) of offspring in the EU.

Following the lack of inter-institutional agreement at second reading, a Conciliation procedure was triggered. In spite of the efforts made and intensive negotiations, a final agreement could not found on the cloning issue and the Ordinary Legislative Procedure was stopped by end of March 2011.

1.2 Objectives and general approach of the study

This study would primarily address the economic, social and ethical considerations and environmental impact linked to the ban of the cloning technique and the setting up of traceability and labelling systems to allow market information on products from clones, their offspring and their descendants.

For these purposes detailed data needs to be collected concerning, for all involved species (bovine, porcine, ovine, caprine and domestic solipeds): the economic, social and ethical considerations and environmental impacts of:

- the suspension of the cloning technique,
- the setting up of traceability mechanisms for semen and embryos from clones, for live offspring; and,
- the labelling of food derived from offspring and their descendants.

A feasibility study and the potential impact on trade of traceability and labelling requirements for all foods (un-processed and processed) needs also to be done.

1.3 User of the contract

Unit SANCO E6 Innovation and sustainability in cooperation with A2 Legal affairs, G2 Animal health, G3 animal welfare, G6 Multilateral international relation, G7 Bilateral international relations, 02 Innovation for health and consumers and the Impact Assessment Steering Group (IASG).

2. TASK TO BE PERFORMED BY THE CONTRACTOR

2.1 Scope of the study

The contractor needs to assess:
-The operational feasibility for putting in place the traceability and labelling requirements for foods derived from cloned animals, their offspring and descendants, both for EU products and third country imported products.

-The socio-economic and environmental impacts of the different measures regarding cloning for food production on the EU farming sector (including breeders and reproductive material centres), the EU food industry and retail/distribution sector and on international trade (imports and exports).

The social impact refers to the potential lost of activity and employment in the farming sector and meat and milk industry which may result from the adoption of the cloning measures. The environmental impact refers to the potential consequences on biodiversity. The economic impact is further detailed under point 2.3 task 2.

This initiative is limited to cloning for food production and is not covering the use of the cloning technique for all other purposes such as research, production of pharmaceuticals or the conservation of endangered species or breeds.

The following issues are covered:

1. Data collection processing and analysis concerning:
- the use in the EU and main third countries: of clones themselves; of reproductive materials from clones; and of live offspring from clones.
- the trade (EU imports and exports) of meat and milk, of meat and milk products and of some derived processed products (such as gelatine, caseins …).
2. Assessment of the technical/operational feasibility of the various cloning measures (ban of the cloning technique, traceability of reproductive materials and of live offspring, traceability of food from offspring and their descendants)
3. Qualitative and quantitative assessment of the economic, social and environmental impact of the measures mentioned in point 2.

This study, taking into account the cloning developments, should cover all species (bovine, porcine, ovine, caprine and domestic solipeds). However the extent of expected work would differ between the different species as the cloning technique for food production is up to now only developed for bovine and porcine species.

2.1.1 Time frame

The data from the period 2006- 2010 (up to last data available) will be covered by the study.

2.1.2. Geographical coverage

EU countries and main third countries trading partners (USA, Brazil, Argentina, Paraguay, Uruguay, Canada, New Zealand, India, Australia and China).

2.1.3 Sectors concerned

The study will analyse the impact on the following sectors:
- EU farmers including breeders and reproductive material centres.
- Meat industry (slaughterhouses, cutting plants and meat processors)
- Milk and milk products industry
- Butchers and retail/distribution sector
- Traders (imports and exports)
- National Competent Authorities (administrative burden and costs)

2.1.4 Actors

Professional organisations and industry representatives from the farming and food sectors of some EU Member States (a representative sample) and main third country partners (USA, Brazil, Argentina, Paraguay, Uruguay, Canada, New Zealand, Australia and China). Companies of cloning in Europe and third countries. National Competent Authorities in EU Member States (A representative sample).

2.2 Study Themes

2.2.1 Theme 1: Economic, social and environmental impact at EU and international level of a temporary or permanent SUSPENSION of

1. the cloning technique in the EU for all food production animals and the use of clones
2. the marketing of food from clones
3. the marketing of reproductive materials of clones (semen, embryos and ova) from third countries or generated in the EU
4. the marketing of live offspring from clones (first generation) i) imported and ii) produced in the EU.
5. the marketing of live offspring from clones of all generations i) imported and ii) produced in the EU.
6. the marketing of food from offspring from clones first generation i) imported and ii) produced in the EU.
7. the marketing of food from offspring from clones all generations i) imported and ii) produced in the EU.

2.2.2 Theme 2: Economic, social and environmental impact of a TRACEABILITY systems for

1. lives clones i) imported and ii) produced in the EU.
2. food from clones i) imported and ii) produced in the EU.
3. reproductive materials of clones (semen, embryos and ova) i) imported and ii) produced in the EU.
4. live offspring from clones first generation imported i) imported and ii) produced in the EU.
5. live offspring from clones all generations i) imported and ii) produced in the EU.
6. food from offspring from clones first generation i) imported and ii) produced in the EU.
7. food from offspring from clones all generations i) imported and ii) produced in the EU.

2.2.3 Theme 3: Economic, social and environmental impact of a LABELLING systems for

1. food from clones i) imported and ii) produced in the EU.

2. food from offspring from clones first generation i) imported and ii) produced in the EU.
3. food from offspring from clones all generations i) imported and ii) produced in the EU.

The data should be presented so that the impact on imported products and products produced in the EU can be assessed separately and as a whole.

2.3.Tasks

The contractor is required to provide the Commission with the necessary quantitative data, as well as analytical and descriptive inputs on economic, social and environmental impacts, as identified in the specific request below. These inputs shall be consistent with the policy requirements, quality and standards necessary to conform to the Commission's Guidelines on Impact Assessment.

The external contractor will be responsible for the collection and collation of the required data taking into account the data provided by the Commission services on statistics and trade figures (TRACES, COMEXT). To this end, the contractor should also consult with all relevant stakeholders, including industry and professional organisations.

Task 1: Observing

Data collection and processing should be performed drawing from desk research, but supported by IT-based expert survey, telephone or face-to-face interviews (as found suitable within the data collection agenda), and broad consultations within the respective Member States and third countries.

Task 2: Analysing

First step is to establish a baseline model of the current situation as regards cloning based on the EU production and trade of live clones and reproductive materials, and an estimate of live offspring and their products on the EU market.

A dynamic economic model based on several scenarios should quantify future direct and indirect economic impacts that are likely to occur (both intended and unintended ones) as a consequence of implementing the three elements (suspension/liberalisation, traceability, labelling); long term general forecast, cost of production, retail prices and market quantities.

Drawing from this model, a qualitative analysis according to several scenarios should be elaborated, taking into account the possible development and use of cloning, the use of offspring and other products, their commercialisation (trade, processing, consumption) based on forecast figures of meat and milk market developments in both the EU and third countries, notably EU export markets and third countries already active in cloning.

Task 3: Overall assessment

Drawing on above quantitative and qualitative analysis, the results of the assessment are to be brought together in a consistent format to allow for assessment of the technical feasibility and the economic, social and environmental impacts of the measures proposed in themes 1, 2 and 3. Conclusions on the advantages and disadvantages of the above measures to be established based on comparison with the baseline scenario.

2.4 Description of the technical requirements and required profiles

2.4.1 Experience required

The following experience is required i) the economic know-how (economic social and environmental

impact) and ii) the operational feasibility of information systems (traceability and labelling) for the whole food chain (from farm to table approach).

2.4.2 Specific skills

The external contractor should be aware of and, where relevant, make use of economic modelling systems to establish projections on market prices and trade flows.

2.5. Additional information

A list of annexes with specific information on the main legislation (animal welfare, traceability of live animals and products and labelling of food) and statistical data on import and export in the EU for reproductive material, live animals and food products will be provided to the contractor.
Other Commission services also have relevant data for this study (such as economic data from DG AGRICULTURE and TRADE).
In addition, European Food Safety Authority Opinions, European Group of Ethics report, Eurobarometer and the Commission report of 2010 on cloning will be also provided.

Other measures taken by the Commission:

-European Food Safety Authority (EFSA) was asked to assess the animal health and animal welfare issues, as well as environmental and food safety aspects. EFSA in July 2008 adopted an opinion in which no indication of any difference in food safety for meat and milk of clones and their progeny compared with conventionally bred animals. In 2009 and 2010 EFSA published two statements confirming the validity of the conclusions and recommendations of the 2008 EFSA opinion.
-The European Group of Ethics (EGE) was asked to present an opinion on the ethical problems raised by the use of animal cloning. EGE in its report of 2008 expressed doubts on the ethical justification on cloning animal for food production purposes, "considering the current level of suffering and health problems of surrogate dams and animal clones". EGE also concluded that did " not see convincing arguments to justify the production of food from clones and their offspring".
-An Eurobarometer was made by the Commission in 2010 in order to know consumer's attitudes and views on such new technology.The Eurobarometer survey in 2010 has shown expectations form the EU citizens to also adopt additional measures as labelling for offsprings.

Animal welfare:
The available EFSA opinion associates animal welfare problems with the current state of the application of the cloning technique. Cloning presents severe welfare challenges for clones arising directly from its use and also through possible exacerbation of the problems caused by selective breeding. These animal welfare concerns do not apply for the production of offspring from clones and their descendants which are obtained through standard reproduction techniques. EFSA opinion provides scientific support for the view that there are adverse animal health/welfare consequences, to which a non-discriminatory and proportionate response could be justified.

Consumer's choice:
In the Eurobarometer of 2010 a majority of EU citizens have concerns about animal cloning and a majority is not willing to accept animal cloning for food production purposes. Furthermore, if food products from the offspring of clones animals become available they would require them to be labelled. The above mentioned food labelling requirements will imply to develop reliable and sofisticated systems of animal identification and traceability in the EU. Developing those systems may have an impact on EU stakeholders (e.g. farmers, industry, etc) which may need to be carefully assessed.

Food safety:
As EFSA did not identify any risks for human health, a definitive restriction on the marketing of cloned products (whether food, semen, embryo etc) in the EU would probably be difficult to justify. Cloned animals cannot be distinguished from conventionally bred animals through any existing method. The same applies to foods from offspring from cloned animals and from conventionally bred ones, which is exactly similar in composition and nutritional value.

Ethical considerations:
The basic ethical issue raised by EGE concerns the moral status that people attribute to animals. The position of society on this issue has broadly evolved along two lines: either animals were seen as mere possessions by their owners and available to them for any purposes that they saw fit, or animals were given respect in varying degrees. These attitudes were influenced strongly by cultural and religious traditions.

2.6 REPORTING AND DELIVERABLES

Inception report.
The evaluator must provide the Commission services with an inception report on the detailed planning of the study, including methodology, and data sources to be used. This document will present in detail how the method proposed is going to be implemented and in particular how the method will assess each element required and provide a judgement. This document will provide the Commission desk-officers with the opportunity to make a final check of the feasibility of the method proposed and the extent to which it corresponds with the information needs outlined in the terms of reference.
The inception report will be submitted at the latest 6 weeks after the signature of the contract.

Intermediate results and progress report
The evaluator must provide the Commission services with a written and oral presentation of the intermediate results of the study including a summary of the main findings for each element to be considered. This progress report will provide the inter-Service steering group with the opportunity to check whether the study is on schedule and whether the preparatory work has actually focused on the specified information needs.
This task will be carried out 3 months after the signing of the contract at latest.

Draft final report and final report

a) Draft final report:
The evaluator must provide the Commission services with a written and oral presentation on the draft final results. The draft final report will provide the conclusions of the evaluator in respect to the elements to be assessed as included in the terms of reference. These conclusions will be clearly based on evidence generated through the analysis. Judgements provided should be clear, objective and explicit. This document will also contain recommendations developed on the basis of the conclusions reached by the evaluator. The structure of the draft final report will respect the structure set up by common standards and include an executive summary (synthesis of main analyses and conclusions, added value of each element), main report (presenting in full the results of the analyses, conclusions and recommendations), technical annexes, and a one-page summary on the Key Messages of the analysis carried out.
The draft final report will be submitted at the latest 5 months after the signature of the contract.

b) Final report
The evaluator must provide the Commission services with a written and oral presentation on the final results at the latest 6 months after the signature of the contract. The final report will take into account the results of the internal quality assessment about the draft final report insofar as they do not interfere with the autonomy of the evaluators in respect to their conclusions. The final executive summary and Key Messages page will be part of it.
The reports and presentations will be provided in English under electronic format compatible with Commission's software. Each deliverable will be followed by a presentation in Commission's office in Brussels.
Deliverables will be submitted to the Commission experts, which may ask for complementary

information or propose adjustments in order to redirect the work when necessary. Deliverables must be accepted by the Commission. With work progressing and in the light of new findings, revisions of deliverables already approved may be necessary.
Deliverables shall be drafted in a concise and easily understandable language. The presentation of the texts, tables and graphs has to be clear and complete and correspond to commonly recognised standards for studies to be published.
The volume of final deliverable text will not exceed 200 pages (Times New Roman 12 or equivalent, excluding annexes). The core text has to be concentrated on the assessment of the main study items. An executive summary of not more than five pages should be included in the final report. Background information should be presented in annexes.

2.7. Organisation and timetable

The analysis will be performed within 6 months from the date of signature of the contract. The contractor is expected to start working immediately after the contract has been signed.
The contract involves regular meetings in Brussels between the commission desk officers and the contractor in accordance with the programme set up in the following table. Deadlines of the table refer to the date of delivery by the contractor to the Commission. Oral presentation should take place in Brussels in Commission's offices within two weeks after the delivery.

Timetable and deliverables

Deliverables	Deadline after signature
Kick off meeting	15 days
Inception report	6 weeks
Electronic presentation intermediate results + progress report	3 months
Draft final report	5 months
Final report	6 months

3.5. Budget
Maximum price: 125,000 €
Administrative Budget line: 170102110004