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IMPACT ASSESSMENT

Accompanying the document

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, and

Proposal for a

COUNCIL DIRECTIVE

on the placing on the market of food from animal clones

{COM(2013) 892 final}
{COM(2013) 893 final}
{SWD(2013) 520 final}

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Executive Summary Sheet

Proposals for Directives of the European Parliament and of the Council on cloning of food producing animals

A. Need for action

Why? What is the problem being addressed?

a) ***Welfare and health of animals linked to the use of the cloning technique***

EFSA[1] highlighted that surrogate dams (carrying the clones) and the clones themselves suffer in the application of the technique.

b) ***The negative perception that EU citizens have cloning technique if used for food production***

In surveys the vast majority (above 80 %) of *EU citizens* expressed *broadly negative perception* of the use of cloning technique for food production. This perception appears to be at least partly the result of:

- the unfounded assumption that cloning of food producing animals poses a risk to food safety and human health;
- the false idea that this cloning involves genetic modification;
- general scepticism towards new technologies in biosciences;
- fear that negative effects of cloning manifest themselves only later.

c) *The request of the co-legislator to address the issue*

Inter-institutional discussions on cloning started in 2009 in the context of the negotiations on a proposal streamlining the approval process of the 1997 Novel Food Regulation. No agreement could be reached between Member States and the European Parliament on any of the issues linked to cloning. The conciliation failed and the Commission was requested to present a proposal on cloning based on an impact assessment.

What is this initiative expected to achieve?

General objectives

To address concerns on cloning for farming purposes, to ensure uniform conditions for farmers in the EU and to protect consumer interests as regard food from cloned animals.

Specific objectives

- *Objective 1:* To ensure uniform conditions of production of farmers in the EU while protecting health and welfare of farmed animals;
- *Objective 2:* To protect consumer interests as regards food from cloned animals;
- *Objective 3:* To safeguard the competitiveness of farmers, breeders and food businesses in the EU

What is the value added of action at the EU level?

Council Directive 98/58/EC lays down general minimum welfare standards for animals bred or kept for farming purposes. It calls on Member States to avoid unnecessary pain, suffering or injury of farm animals. If cloning causes unnecessary pain, suffering or injury, Member States have to act at national level to avoid it.

Yet different national approaches to animal cloning could lead to market distortion. Measures regulating the use of the cloning technique would address the associated animal health and welfare concerns. They would prevent the development of diverging national legislation and the consequent disruptions of the concerned agricultural markets. They would thus also ensure level playing field for breeders and farmers and uniform conditions of production for farmers.

[1] opinion of 2008 up-dated in 2009, 2010 and 2012

As breeding/cloning companies and food operators in third countries are also concerned it is necessary to ensure that the same conditions apply to them. The matter should thus be addressed at Union level.

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

Four legislative policy options have been assessed: (1) the status quo; (2) premarket-approval of food from clones, offspring and descendants; (3) labelling of food from clones, offspring and descendants; and (4) suspension of the cloning technique in the EU (with the suspension of use of clones, their reproductive material and their food).

None of the options would on their own enable to attain the objectives. Therefore to define the most appropriate policy approach, elements of options may need to be put together. No preferred option is thus proposed at this stage.

Who supports which option?

All professional organisations representing the various farming, breeding and food industry sectors are in favour of the status quo and resist new measures on cloning as they may trigger additional costs and administrative burden. Conversely, the European consumer organisations and other NGOs are in favour of a mandatory labelling of food products derived from the progeny (offspring and descendants) of clones and the suspension of the cloning technique in the EU.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

This option has a positive impact on animal welfare and creates a level playing field for all farmers and breeders in the Union. It is restricted to the technique, to clones and food obtained thereof. Its impact on Union FBOs and trade is limited because trade, if any, is likely to be insignificant as FBOs have no interest to market food from clones. The suspension of the technique would not stifle innovation and research as it would be temporary and limited in scope. It thus signals that research outside this policy can be pursued.

Traditional breeding techniques use clones to produce offspring. Hence the suspension of the use of reproductive material of clones could jeopardize the competitiveness of the Union's farming sector as it would deprive it of competitive genetic material.

This option has a positive impact on consumers: their concerns about animal welfare will be addressed as no cloning would take place in the Union and no food from clones marketed in the Union.

What are the costs of the preferred option (if any, otherwise main ones)?

The impact of the preferred option on business is negligible as trade in animal clones and food derived thereof is quasi non-existent and food business operators have no commercial interest in marketing clones or food from clones.

How will businesses, SMEs and micro-enterprises be affected?

The freedom to conduct business might be restricted but this would be justified for the purpose of protecting animal health and welfare and the suspension would be stopped as soon as the technology has evolved. The Directives will not have an impact on SMEs and micro-enterprises

Will there be significant impacts on national budgets and administrations?

There would be no additional costs for Member States' control authorities as official controls are already in place on animals and their reproductive material, as well as on food labelling in general.

Will there be other significant impacts?
The preferred option could have indirect long term effects on the allocation of innovation investments. Organisations looking to invest in the development of cloning in general may be more inclined to place their investments elsewhere. Therefore we need to continue to encourage cloning for research.
D. Follow up
When will the policy be reviewed?
Both proposals trigger a review process By 5 years after the date of transposition of this Directive when Member States will have to report to the Commission on the experience gained by them on the application of the Directives.

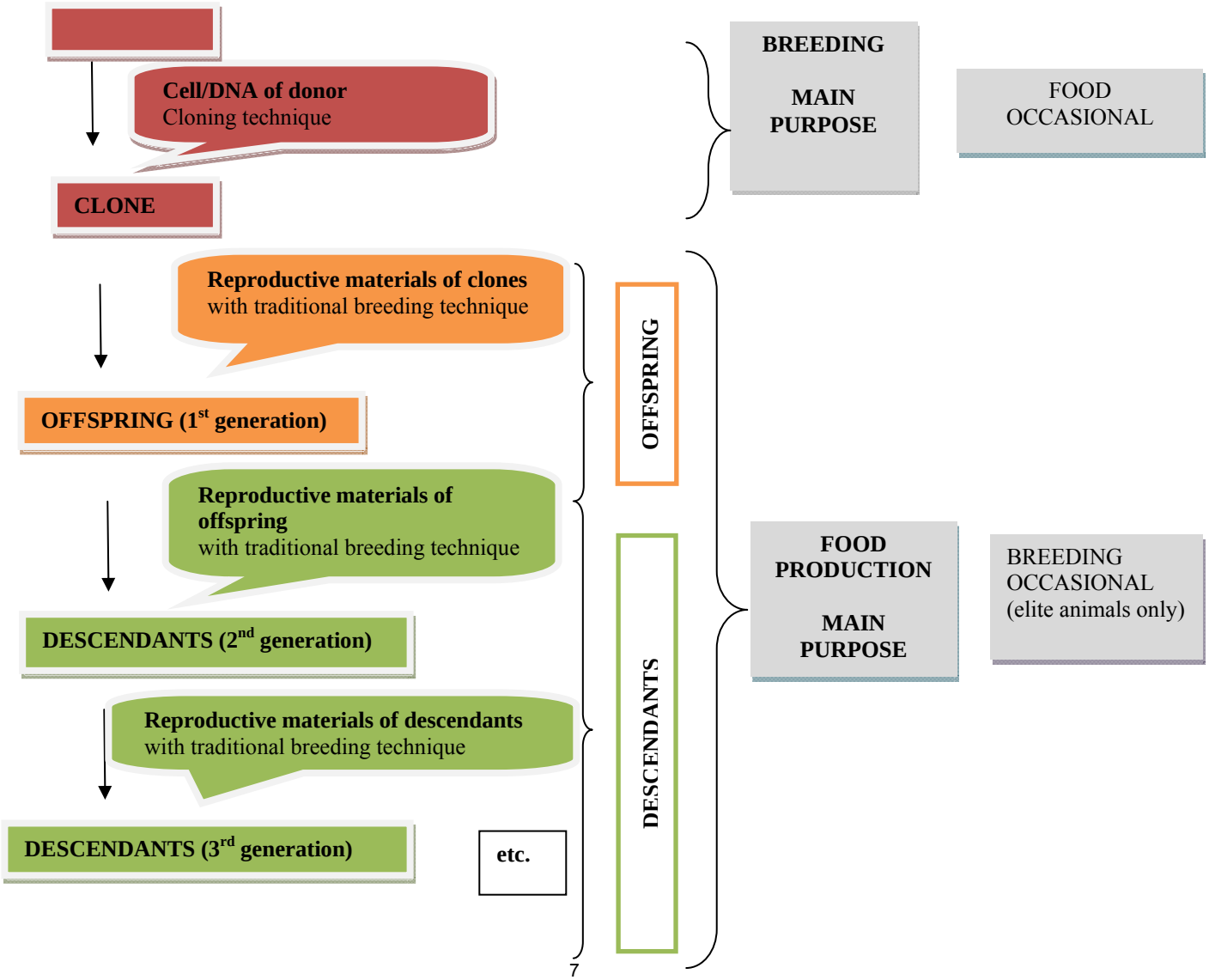
1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Introduction

Cloning is a relatively new reproduction technique which allows the asexual reproduction of an individual farm animal that has shown good productivity. Cloning does not involve any genetic modification. In fact, the clone is a near exact genetic copy of the original animal (the donor) and should have the same high quality reproductive material (semen, ova or embryos) as that of the donor. Although cloning does not *improve* the animal's performance, breeders may consider cloning beneficial in order to *increase* the output of reproductive material of a particularly valuable animal.

Clones for food production are used to produce reproductive material. As shown in the schema below, the reproductive material of the clone enables the production of progeny (composed of offspring and then of descendants). This progeny is produced via traditional breeding techniques (not involving cloning). It is mostly destined for direct use in the food chain although elite animals may be retained for breeding purposes.

Clones are not produced to obtain meat or milk for the food chain. This may however happen for meat, at the end of the breeding life of the clone or when the clone obtained is less efficient than originally foreseen and therefore no longer kept for breeding purposes. The process of cloning is further detailed in Annex XIII (Paragraph 1).



As cloning is a novel reproduction technique and as food from clones is susceptible to enter the food chain, food from clones is presently subject to a pre-market approval under the existing Novel Food Regulation[2]. The inter-institutional discussions on a proposal streamlining this approval process reached a stalemate on issues related to cloning (such as the use of the technique in the EU, the use of reproductive material of clones, of their food, the traceability of progeny of clones and of their food). In spite of the Commission's report of October 2010, which suggested adopting specific measures on cloning[3], no agreement could be reached and the Conciliation ended in March 2011. This led to the request to the Commission[4] to prepare a separate legislative proposal on all aspects of cloning for food production based on a detailed impact assessment.

This impact assessment therefore covers the five species susceptible to be cloned (i.e. bovine, porcine, caprine, ovine and equine) and used for food production. Cloning of animals for research purposes, for producing medicinal products or medicinal devices, for preserving rare breeds or endangered species or for sport purposes is excluded from this policy initiative. A Glossary of technical terms is to be found in Annex I.

1.2. Organisation and timing

The public consultation and collection of expertise took place between end 2011 and end 2012.

1.2.1. Member States

Member States were consulted in the meetings of Standing Committee for the Food Chain and Animal Health between February and July 2012 to clarify whether cloning takes place and if so to what extent, and were subsequently invited to respond to a specific questionnaire on these issues in March 2012. All 27 Member States responded with Germany authorities clarifying their final position in May 2013.

In response to the questionnaire on the use of cloning on their territory, to know whether clones are produced for food production or imported and if so to what extent, all Member States confirmed that cloning for food production does not take place on their territory. Most of them specified that Directive 98/58/EC[5] (see section 2.6.1) is transposed into national animal welfare law. Only Denmark refers explicitly to cloning which is banned on their territory. Germany who reported in the past the existence of cloned bulls for selling their reproductive material outside the EU confirmed in writing in May 2013 the absence of any such clones on their territory. France reported cloning of horses but only for sport purposes. The positions of Member States are summarised in Annex III (paragraph 1).

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[2] Regulation (EC) N° 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel food ingredients.

[3] Report from the Commission to the European Parliament and the Council on animal cloning for food production COM (2010) 585 of 19.10.2010 suggested to (i) to suspend temporarily the use of the cloning technique, clones and of food from clones for five years; (ii) to trace imported reproductive materials of clones. http://ec.europa.eu/dgs/health_consumer/docs/20101019_report_ec_cloning_en.pdf

[4] For example, the European Parliament resolution of 6 July 2011 on the Commission Work Programme 2012 requested a legislative proposal to prohibit food from clones, offspring and descendants: http://www.europarl.europa.eu/sides/get

[5] Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes; see in particular Article 3 and 4 and Point 20 of its Annex.

1.2.2. Stakeholders and third countries[6]

Multi stakeholders meetings took place via the Advisory Group of the Food Chain (Annex II) with 22 organisations representing all concerned stakeholders (farmers and breeders, meat and milk industry, food industry, retail industry, consumers and animal welfare) on their position on possible action regarding the use of the cloning technique in the EU and the appropriateness to label food from clones and of their progeny so as to offer consumer choice.

Five technical bilateral meetings were held with specific industry organisations on technical issues linked to breeding for food production to understand the baseline scenario regarding traceability of animals and of meat and milk. The minutes of the meetings are to be found in (Annex II).

15 third countries with major trade (in meat, milk products and reproductive materials) with the EU were also consulted via a specific questionnaire sent in March 2012. 13 countries responded to the questionnaire and one (New Zealand) sent instead a letter expressing their position. China and Chile did not reply to the questionnaire.

Based on the responses received to the questionnaire on cloning activities to understand whether traceability systems are in place for clones, their progeny and food, the responses received can be summarised as follows: cloning for food production takes place in USA, Canada, Argentina, Brazil and Australia. In Canada the situation on cloning is similar to that in the Union, i.e. food produced from food is considered novel and requires pre-market approval. In the other countries, clones, their progeny and reproductive material are subject to the same regulation as conventional animals regarding the food safety, animal health and welfare. Clones are registered by private companies (USA, Canada and Brazil)[7] but Argentina and Australia report that clones are not registered. The number and activities of cloning companies on their territory are not known by any of the authorities. The positions of third countries are summarised in Annex III (Paragraph 2).

1.2.3. Responses to the public consultation "IPM consultation" & position papers

The *public consultation* was launched in March 2012 via the Interactive Policy Making (the so called "*IPM consultation*") for 16 weeks with reminders sent during this period via the Enterprise Europe Network, on DG Health and Consumers website and via the e-news network reaching approximately 6000 subscribers: 360 replies were received among which 34 from professional organisations, 34 from non-governmental organisations, 10 from Member States, one third country and 230 from individuals.

Almost all[8] professional organisations representing farmers, breeders, food industry and retail, when asked about policy change on any of the issues of cloning indicated their favourable position towards the status quo (no legislation on cloning, maintaining food from clones under the Novel Food Regulation, no measures on food from progeny of clones, no labelling). The additional position papers received from industry (farmers,

[6] For the selection of these third countries see Annex III (Paragraph 2).

[7] Breeding companies in third countries and as, in the USA, organisation and data base sponsored by industry of a "supply chain management system" to track clones and exclude them from the food supply chain the data bases in the USA and Canada contain the DNA profile of the clones. See Annex XIII Paragraph 4).

[8] EuroCommence considers that "should food methods from clones and offspring be authorised for the EU market, a practical solution needs to be found to enable traceability of these products along the whole food supply chain".

breeding sector and food industry) confirmed that the current situation represents for them the best scenario.

Conversely consumer organizations, animal welfare associations and individuals, expressed themselves against the use of cloning technique and the placing of the food from clones and their progeny on the EU market. Finally, EU citizens participating in the "IPM consultation" emphasised that if food products originating from clones and their progeny would be available on the EU market, they would want to be able to make informed choices.

The responses to the IPM consultations are summarised in Annex IV. The position papers of specific stakeholders are summarised in Annex III (Paragraph 3).

1.2.4. Results of Eurobarometer of 2008 and 2010

To understand the consumers' position, a specific Eurobarometer of 2008 on cloning[9], which surveyed 25000 randomly selected citizens in EU 27 and the 2010 Eurobarometer on biotechnology of were used.

The Eurobarometer of 2008 on cloning showed that around 80% of the interviewees agreed that there could be ethical grounds for rejecting animal cloning and around 70% that animal cloning would risk treating animals as commodities rather than creatures with feelings. Concerning animal welfare issues linked to the use of cloning technique, 41% agreed that it would cause animal unnecessary pain, suffering and distress and 42% disagreed. In the Eurobarometer on biotechnology of 2010 EU citizens expressed strong reservations about the use of animal cloning in food production. More information on the responses is available in Section 2.2. (concerns of EU citizens).

1.2.5. Impact Assessment Steering Group (IASG)

The *Impact Assessment Steering Group* (IASG) was set up in November 2011 with 11 Directorate-Generals as well as EFSA: DG AGRI, ENV, TRADE, MARKT, RTD, JUST, ENTR, TAXUD, JRC, SG and LS. The Group was consulted frequently. It agreed on the Roadmap in February 2012[10] and dealt with the work carried out by the contractor, the *IPM public consultation*, the consultation process with Member States and third countries as well as the elaboration of this impact assessment report.

1.2.6. External expertise

The *European Food Safety Authority* (EFSA) delivered an opinion in 2008 on the food safety, animal health, animal welfare and environmental implications of clones, of their progeny and of the products obtained from those animals followed by three statements in 2009, 2010 and 2012[11]. Based on the available data EFSA confirmed the welfare problems related to the health of surrogate mothers (carrying the clones) and clones themselves. Regarding food safety, EFSA concluded that there is no indication of any difference for food safety for meat and milk of clones and their progeny compared with those of conventionally bred animals.

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[9] Europeans' attitudes towards animal cloning http://ec.europa.eu/public_opinion/flash/fl_238_en.pdf

[10] http://ec.europa.eu/governance/impact/planned_ia/docs/2013_sanco_007_use_of_cloning_technique_for_food_production_en.pdf

[11] 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 ;
http://www.efsa.europa.eu/en/efsajournal/doc/319r.pdf;
http://www.efsa.europa.eu/en/efsajournal/doc/1784.pdf ;
http://www.efsa.europa.eu/en/efsajournal/doc/2794.pdf

The specific report on cloning by the *European Group on Ethics* in Science and New Technologies (EGE) of 2008[12] was also used as source of expertise. The EGE expressed doubts on the ethical justification on animal cloning for food production purposes, "considering the current level of suffering and health problems of surrogate dams and animal clones". EGE also concluded that it did "not see convincing arguments to justify the production of food from clones and their offspring".

In December 2012 *a study*[13] *by ICF-GHK* was finalised concerning mainly the feasibility and costs of the possible measures on animal cloning (summary in Annex V).

1.3. Opinion of the IAB

The IA report was submitted to the IA board on 19. June 2013 and was formally presented on 17 July 2013. Following this meeting the board issued a positive opinion on 19 July 2013. The opinion suggested clarifying a number of points, which have been addressed in the following manner:

1) Explain better the uncertainty in interpreting Directive 98/58/EC as regards the use of the cloning technique, its potential circumvention and the likelihood of unilateral national measures and explain better why the existing pre-market approval would still be considered fit for purpose for food from bovine and porcine clones.

These issues have all been addressed in section 2.3. "risk of diverging national laws on cloning" and section 2.6.1. (b) "Novel Food Regulation".

2) Explain why measures to improve consumer awareness or upgrade/revise existing voluntary (organic) label schemes have not been considered, give further insights into consumers views clarify whether there is any evidence of undermined consumer confidence because of absence of information on cloning, and to what extent consumers are ready to pay higher prices, and why food business operators have not developed voluntary labelling schemes.

This explanation has been added in section 2.2. on "concerns of EU citizens" and in section 2.4 "the underlying drivers".

3) Present and asses the provisions on "mandatory" and "voluntary" labelling versus "offspring" and "descendants" separately and clarify the proportionality of option 2 and explain difference between status quo and labelling food from clones/suspension of the cloning technique.

This has been done in section 5.2.1. "description of option 2" and in section 4.1. "Policy options". In addition, sections 5.3. , 6.1., 6.2. and 6.3. present and assess the options distinguishing between "offspring", "descendants", "voluntary", "mandatory".

4)Provide (as appropriate) a more conclusive assessment of competitiveness impacts, clearly differentiating between the impact on EU farmers, importers of food and the food chain industry operators, clarify readiness of third countries to put in place the traceability systems. These requests have been dealt with in section 5.3.3.(b) and (c) and overview tables (numbers 4 and 5) has been inserted in Annex IX.

[12] Ethical aspects of animal cloning for food supply 16 January 2008: http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion23_en.pdf

[13] Source ICF-GHK study on animal cloning December 2012.

5) Section 5.1 on the pre-market approval of food from clones and section 5.3.2. (a) on the labelling of food from clones explain why the related costs would be marginal. Regarding food from offspring and descendants, section 5.3.2. (b) explains the costs of traceability and labelling.

6) Identify which Member States will be impacted most and explain how the 2 % increase in the beef sector has been calculated. This has been integrated in Annex IX.

7) Clarify why national authorities / EU budged are not expected to bear additional costs: The clarification has been added to section 5.5. "Impacts on control".

8) Give the key results in a comprehensive overview table: Table 9 has been added in Section 6. In view of the many possible options, in particular on labelling, this table 9 is a summary of the more elaborate overview which is to be found in Annex XII.

9) Mention monitoring indicators corresponding to the data collection and respective objectives: this data has been added in section 7.

10) Complete Summary and Executive Summary sheet with most relevant information: this has been done.

2. PROBLEM DEFINITION

As indicated under 1.2.6. above EFSA concluded that there is no indication of any difference for food safety for meat and milk of clones and their progeny compared with those of conventionally bred animals.

2.1. Animal welfare concerns linked to the use of the cloning technique

In the EFSA's opinion on animal cloning of 2008 and subsequent statements until 2012 it is highlighted that issues of welfare and health of animals for the surrogate dams (carrying the clones) and the clones themselves are arising. This evaluation is however based on limited data and related primarily to bovine and porcine species. In particular:

a) *For bovine and porcine species* EFSA noted that 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 about 6 % for porcine species) and the need implant embryo clones[14] into several dams to obtain but one clone. In addition, clone abnormalities and unusually large offspring result in difficult births and neonatal death. After weaning no significant differences from conventional animals are noted.

b) *for other species (ovine, caprine and equine),* EFSA stated that there was not enough data available to complete its assessment on animal welfare aspects.

c) As regards *offspring and descendants of clones,* EFSA concluded that no animal health or welfare problems affect offspring and descendants of clones, as compared to conventionally bred animals, for all species as they are produced, via traditional reproduction techniques.

[14] *Embryo clones* need to be distinguished for the "*embryo*" classified under reproductive material. The first is a clone, the second not.

2.2. Concerns of EU citizens

The vast majority (above 80 %) of EU citizens interviewed in the Eurobarometer survey had a broadly negative perception of the use of cloning technique for food production[15]. This was primarily due to welfare and ethical concerns. EU citizens also indicated that if food products originating from clones and their progeny would be available on the EU market, they would want to be able to make informed choices. Half of the interviewees also considered – incorrectly- that animal cloning involves genetic modification.

This is highlighted by both the 2008 and 2010 Eurobarometer and the IPM consultation launched for this impact assessment (see chapter 1.2.4. above).

This strong negative perception of cloning appears to be at least partly the result of:

- the unfounded assumption that cloning of food producing animals poses a risk to food safety and human health;
- the false idea that this cloning involves genetic modification;
- general scepticism towards new technologies in biosciences;
- fear that negative effects of cloning manifest themselves only later.

2.3. Risk of diverging national laws on cloning

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.

Member States may ban explicitly the use of cloning technique on their territory in accordance with provisions of Directive 98/58/EC on animal welfare on all species or only on some of them. Directive 98/58/EC forbids the use of "breeding procedures which cause unnecessary pain" but does not explicitly forbid the cloning technique. Denmark adopted in 2005[16] a national legislation which forbids the use of the technique on the national territory but does not regulate the intra-Union trade and the imports of animals, their reproductive material or food. It therefore has no impact on the functioning of the internal market. However, it is not certain that other Member States, when taking national measures, in the absence of EU initiatives would take a similar line as Denmark. They may interpret the provision of the Directive in a way that the use of clones, whether produced nationally or imported, and their products (reproductive material and food) are also forbidden on their territory.

There is no information about the circumventing of the de-facto ban on the use of cloning technique as there is no legal requirement for EU operators to register any information related to the cloning status of their animals or informing the competent authorities when

[15] EU citizen concerns were threefold (in descending order % of replies, see page 11 of the summary http://ec.europa.eu/food/food/resources/docs/eurobarometer_cloning_sum_en.pdf)
1. (84%): the EU do not know enough about the long term health and safety effects of using cloned animals for food.
2. (75%): Cloning for human consumption could not be seen just as a technical issue, since there could be ethical grounds for rejecting such cloning.
3. (69%): using cloning for food production purposes would be unacceptable because it would mean that animals are treated as commodities rather than creatures with feelings.

[16] LOV nr 550 af 24/06/2005 - Lov om kloning og genmodificering af dyr m.v https://www.retsinformation.dk/Forms/R0710.aspx?id=2116

buying a clone or its reproductive material (same requirements as for conventionally bred animals).

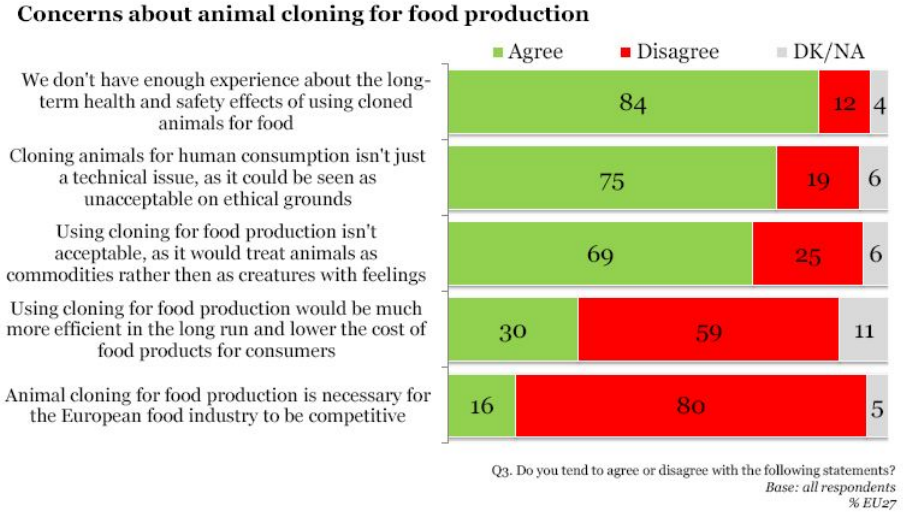
During the Conciliation referred to in paragraph 1.1.above, Member States expressed their willingness to see measures on cloning at EU level but did not specify which type of national measures they would adopt in the absence of EU initiative. Taking into consideration the outcome of the inter institutional debate on food from clones, it appears that the absence of comprehensive EU measures on cloning could present some challenges to the good functioning of the concerned markets as divergent national legislations could be adopted by Member States. However, since the end of the conciliation (as referred to in paragraph 1.1. above), only Austria highlighted in writing the need to address cloning at EU level to avoid adoption of diverging national laws without specifying to which aspects such laws would refer to.

2.4. The underlying drivers

They are three-fold and can be summarised as follows:

- The *animal health and welfare problems* identified by EFSA are due to the use of the cloning technique and its current level of development. EFSA clearly indicates that the negative effects have been observed in other assisted reproductive techniques (not involving cloning) but at much lower frequencies[17]. In the latest update of 2012, EFSA concludes[18] that the scientific knowledge available has increased but that only limited progress has been achieved to diminish or solve of the problems identified as the efficiency of cloning is still low compared to other techniques; in particular, EFSA mentions that to overcome the relative low cloning efficiency, researchers continue to amend cloning procedures, with however limited improvements shown by some researchers.

- The *consumer's attitude* towards the cloning has been summarised as follows in the 2008 Eurobarometer study (page 11 of the summary):



[17] EFSA opinion of 2008 and Statement of 2012
[18] EFSA Statement of 2012 overall conclusion p.18.

It is thus a general negative perception of this reproduction technique generated by different motives.

This general negative perception give rise to a desire to recognize the food derived from clones and their progeny as clearly shown by the survey's results.

The results show that consumers are reluctant to buy products of cloning origin. There is, however, no evidence that buying behaviour for food of animal origin would in practice be influenced by the knowledge on the reproduction technique used.

It is not clear to what extent consumers are ready to pay a premium for information on the food from clones and their progeny. Respective questions were not asked in the context of the various consultations held[19] due to the known discrepancy between the consumers' replies to such questions and their actual purchasing behaviour. The situation is thus not comparable to that of the BSE crisis[20].

- The request to *produce a dedicated policy* on cloning is due to the outcome of the discussions on the Novel Food legislative proposal (see Section 1.1.), where it appeared necessary to clarify and address all different aspects related to cloning going beyond the food aspects. In this context, the Member States already requested the Commission to prepare a proposal on all aspects of cloning, based on an impact assessment. As the conciliation did not conclude, the final positions of Member States and Parliament remain unclear. More specifically Member States requested by unanimity a pre-market approval for food from offspring in first reading but in the subsequent discussions it appeared that some Member States were in favour of labelling and others were totally opposed. The European Parliament[21] requested a ban of the technique, of meat and dairy products of clones and of their offspring as well as of their reproductive material, and then, in second reading, a total ban of any food from clones and descendants[22]. More recently in the context of the discussions of electronic identification of bovine[23], the European Parliament requested mandatory labelling of fresh meat of offspring of clones pending the presentation by the Commission of the specific proposal on cloning.

2.5. Who is affected, in what ways, and to what extent?

The range of actors that could be potentially affected by any measure taken covering the three aspects of cloning (technique of cloning, live animals, their reproductive material and their food) is very wide and include the following :

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[19] i.e. the 2008 and 2010 Eurobarometer and the IPM consultation for the cloning study

[20] The lack of consumer confidence in beef following the crisis in 2000 resulted in a severe drop of beef consumption which was solved through a set of EU measures, including the mandatory labelling of the national origin[21] European Parliament Resolution of 3 September 2008 on the cloning of animals for food supply.
http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2008-0400&format=XML&language=EN

[22] European Parliament Resolution of 7 July 2010 on Novel Food.
http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2010-0266&format=XML&language=EN

[23] The Conciliation on this proposal failed in May 2013.
http://ec.europa.eu/food/animal/identification/bovine/elec_id_bovine_en.htm

- The *breeders,* which produce and market the reproductive materials (semen, embryo and ova) to improve the genetic performances of farm animals for the meat and milk production or other relevant traits. The sector is composed of cooperative of farmers or specific companies specialised in livestock genetics. They may be affected in so far as they presently import reproductive material from third countries some of which could derive from clones. They import limited numbers of live animals but these could also be clones or offspring or descendants of clones, in which case they would also be impacted.

- The *farmers (or livestock sector),* which raise animals for food production, which accounts for a large part of the EU agricultural output (41% of in value terms, representing 1.2% of the European Union's GDP); they may be impacted when they buy reproductive material of clones to raise offspring and subsequently descendants on the EU territory of food production.

-The *EU food industry* at the different stages of the food chain (from slaughterhouses to distribution and retail) when using food from clones, offspring or descendants of clones raised in the EU or importing such food from third countries. SME's play a key role in the EU food sector on every stage of the supply chain, representing nearly 452 billion € of turnover (Annex X).

-*Third country operators* who trade live animals, reproductive material, or food with the EU would also be affected. This would be in particular the case of cloning companies and breeders who may produce reproductive materials from clones (or from offspring or descendants of clones) and export it to the EU; it may also affect food operators in third countries who export meat, milk or the derived products to the EU and which could derive from clones or progeny of clones

- *EU consumers* as purchasers of the food products available on EU the market.

2.6. Baseline scenario

2.6.1. EU legal framework

a) Legislation on animal welfare

The EU Directive 98/58/EC on the protection of animals kept for farming purposes[24] does not refer explicitly to cloning but requires Member States to act at national level to avoid unnecessary pain, suffering or injury in the context of raising farm animals and mentions that such obligation also applies in the use of reproduction techniques. In so far as cloning causes unnecessary pain, suffering or injury, as highlighted by EFSA it cannot be used for food production on the EU territory pursuant to this Directive. The feasibility and the appropriateness of introducing specific welfare indicators to ensure uniform application of EU legislation is being studied under the Welfare Strategy[25].

b) Novel Food Regulation

The Novel Food Regulation[26] covers, to date, the food derived from cloned animals, which are subject to a pre-market approval and a risk assessment by a national competent authority. If an authorisation would be granted mandatory labelling could be requested on a case by case basis. The cloned animals and their food would need to be identified as

[24] OJ L 221, 8.8.1998, p. 23

[25] Communication from the Commission to the European Parliament and the Council on the European Union Strategy for the Protection and Welfare of Animals 2012-2015, COM(2012) 6 final/2 15.2.2012 http://ec.europa.eu/food/animal/welfare/actionplan/docs/aw_strategy_19012012_en.pdf

[26] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients OJ L 43, 14.2.1997, p. 1

"clones" or "derived from clones". To date this identification system dedicated to cloned animals is not in place. Moreover no request for authorisation has ever been made up to now (see further details in Annex V).

c) Legislation on identification of animals

The EU legislation on identification of animals is a prerequisite for the traceability of animals in case of disease outbreaks.

Animal identification systems are established with Regulation (EC) 1760/2000[27], Council Directive 2008/71/EC[28], Council Regulation (EC) 21/2004[29] and Commission Regulation (EC) No 504/2008. These measures provide for mandatory identification devices or marks, passports and registers. All equine animals are identified individually[30] for their life time and registered in databases. Bovine, caprine, and ovine species[31] are in principle identified individually but are subject to some exceptions granted to Member States. Porcine animals are not identified individually; they are identified in "batches" (i.e. same registration number for each pig belonging to the batch).

In addition, all holdings have to record the individual animals (or the batches, in the case of pigs) as well as their movements in their own registers.

No system requires information on the reproduction methods the animals were produced with. It is thus nowhere specified whether the animal is or not a clone or a progeny of clone.

All five species can only be moved between Member States or imported into the EU when accompanied by a "health certificate" delivered by an official veterinarian of the Member State or the third country of dispatch.

Further details are given in Annex VI.

d) Legislation on identification of reproductive material and traceability of the reproductive material to an individual animal

The EU legislation requires - for both imported and EU produced reproductive material- the individual identification of the donor animal. The precise identification of the animal needs to be indicated on the straws, or ampoules, or packaging, or the accompanying "health certificate".

There is no requirement to specify that the donor is or not a clone or a progeny of clone.

Further details are given in Annex VI.

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[27] Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97, OJ L 204, 11.8.2000, p. 1

[28] Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs, OJ L 213, 8.8.2008, p. 31

[29] Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC, OJ L 5, 9.1.2004, p. 8–

[30] Universal Equine Life Number (UELN).

[31] Where derogations are applied in specific Member States for certain or all stock of the ovine and caprine species, the animals have to be registered by batches in the national data bases.

e) Legislation on traceability of animals

Traceability of animals is the ability to track an animal or a group of animals from one point in the supply chain to another, either backwards or forwards.EU legislation imposes traceability systems for the purposes of animal health to provide the information required to implement control measures against disease. They allow that animals can be traced from holding of birth to death/slaughter.

Further details are given in Annex VI.

f) Legislation on traceability of food from animals

Traceability of food is imposed on all food business operators (FBOs) established in the EU by the General *Food law*[32]. FBOs must be able for any food and through all stages of production, processing, and distribution, to identify the immediate supplier of the product in question as well as the subsequent recipient. FBOs organise their production by batches (groups of products with homogeneous characteristics) so as to be able to identify the batches which contain the food to be withdrawn in case of fraud or food safety issue.

This system does not ensure that food (such as a piece of meat) can be traced to an individual animal.

The compulsory labelling system established with Regulation 1760/2000 obliges food business operators to label the beef at all stages of the marketing process and thus to establish the underlying identification and traceability system to allow them to provide the information required, i.e. country where the animal was slaughtered, the license number of the slaughterhouse, the country where cutting was performed, the license number of the cutting plant, the country where the animals were born, the country where the animals were fattened/bred. Imported meat for which not all compulsory information is available is labelled "Origin: non-EC", followed by the name of the third country in which it was slaughtered.

Further details are given in Annex VI.

g) Legislation on zootechnics and voluntary guidelines

To be entered in a herd-book of the same breed, purebred animals of all five species and their genetic material must comply with EU requirements (e.g. parents and grant parents of that breed must be registered in the same herd book and mentioned on the certificate)[33]. Compliance is attested in specific "zootechnical certificates".

There is no EU requirement to register clones specifically in herd books. However, for a particular dairy cattle breed, guidelines have been established on a voluntary basis by the World Holstein Friesian Federation (WHFF)[34] on how to register clones, the donor animal and the required ancestors. It is not known how far this is implemented by

[32] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

[33] http://ec.europa.eu/food/animal/zootechnics/legislation_en.htm

[34] http://www.whff.info/search/index.php.

breeders, whether it exists for other breeds and how much attention EU breeders and farmers give to this information.

Further details are given in Annex XIII (Paragraph 5).

2.6.2. Baseline scenario regarding the farming, breeding and food sectors

The EU livestock production accounts for 41% of agricultural output in value terms, representing 1.2% of the European Union's GDP. In value terms, beef and milk represent over 50% of total output, with sheep meat representing over 20%[35].

Regarding number of actors across the meat and dairy supply chain, there are almost 8 million farmers/producers, around 80.000 processors and the same amount of wholesalers and close to 700.000 food and specialist meat and dairy retailers across Europe[36].

The **EU food sector** represents[37] a total turn-over of 1,017 Billion € and approximately 287,000 companies employing 4.25 million people in the EU. Around 98 % companies are SMEs which represent around 49 % of total turn-over and 63% of employment in the sector. It is the largest manufacturing sector in terms of turnover, value added and employment. It contributes for around 15 % of EU gross value added of manufacturing sector.

SMEs play a key role in the EU food sector, at every stage of the supply chain. They represent nearly EUR 452 billion of turn-over, with EUR 93 billion of value added and employ about 2.7 million people in 271,000 enterprises which are 99.1% of total Food & Drink companies, and 48.7% of total turnover[38].

The **meat consumption** is expected to remain high. On a per capita basis, EU meat consumption in 2022, at 82.6 kg, would be at approximately the same level as it was in 2009. Pork is expected to remain the preferred meat in the EU with 40.8 kg/capita consumption in 2022, compared to 24.1 kg for poultry, 15.7 kg for beef/veal and less than 2.0 kg for sheep and goat meat. Meat demand in Northern America and Europe would remain globally stable by 2050[39] but still remain highest in the world by 2050 at around 89 kg per inhabitant (against an estimated 83 kg in 2010).

Regarding the **economic performance**, gross profit margins are generally not high in the livestock sector but they are positive. However, measured by economic profit and thus also taking into account estimates of the unpaid family factors is negative in most cases, which suggests that resources are not being optimally allocated[40]. Thus, across the food chain, efficiency gains through technological or process innovation are being pursued, which is also a factor leading to concentration in the sector.

The **structure of livestock breeding** in Europe is primarily composed of elite breeders at the top (mostly organised in cooperatives owned by farmers, which are often SMEs) who supply commercial herds in charge of meat and milk production.

[35] Eurostat data 2011.
[36] Eurostat Structural Business Statistics (2009).
[37] Source Food Drink Europe – data & trends of European Food and Drink Industry 2012.
[38] Food Drink Europe: Data trends 2012.
[39] Food and Agriculture organisation – livestock's long shadow – environmental issues and options (2006).
[40] European Commission 2011: 'EU Beef farms report 2010', DG AGRI 2011.

Cloning for food production is not taking place in the EU as reported by Member States (see Section 1.2.1. above) and there is little prospect of commercial cloning activity in the period to 2020, or at least to any significant scale..

The actual impact of cloning on **farm-level economics** can be estimated as providing an annual increase in milk yields of 300kg (estimate for a period of ten years)[41]. For comparison, it is necessary to know that current high end producers are at an EU average of 7000 kg per annum which would mean cloning could provide for an additional increase of 4%. This has to be put into comparison to the current EU dairy market: over the last 3 years, milk deliveries remained relatively stable, with only small variations while forecast for 2020 predict EU-27 total milk production to exceed the 2009 level by about 3%[42].

Further details are given in Annexes VII and VIII.

2.6.3. International dimension

a) Legal framework

For live animals, animal products (including reproductive materials and food), the following multilateral agreements of the World Trade Organization (WTO) are relevant: the General Agreement on Tariffs and Trade (GATT), the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). The precise determination which of the WTO provisions are relevant would depend on the objective and the drafting of the envisaged legislation.

Any measure adopted would have to honour the principle of "National Treatment", which prohibits less favourable treatment of like products imported (Article III: 4 GATT). Departures from this general rule could be justified under Article XX of GATT (General Exceptions) which allows for measures taken on grounds of "public morals", which could be interpreted as including animal welfare or for measures taken on grounds of the protection of life and health of human or animal health. The WTO exemptions are subject to strict requirements, amongst others, proof of the necessity of the measure to obtain the objective in question, which implies that it has to be investigated whether there is not a less trade restrictive way to obtain the same objective, as well as proof of application in a non-discriminatory, non-arbitrary manner. In addition to the GATT, the envisaged legislation would be subject to either the SPS Agreement or the TBT Agreement, depending on its objective and design.

The SPS Agreement applies to measures taken with the objective to protect human, animal or plant health from diseases carried through food, feed, animals, plants or pests. A measure that conforms to international standards is presumed to be in compliance of the SPS Agreement, but there are no international standards on cloning. The SPS Agreement requires measures within its scope to be based on science, proportionate and non-discriminatory.

To the extent the legislation lays down *product characteristics or related processing methods, labelling, packaging or other requirements*, and these requirements do not relate to SPS objectives, the TBT Agreement would apply. The TBT Agreement requires

[41] Dematawewa, C.M.B., & Berger, P.J. 1998: "Break-even cost of cloning in genetic improvement of dairy cattle". Journal of Dairy Science 81(4): 1136-1147.

[42] European Commission 2010: "Evolution of the market situation and the consequent conditions for smoothly phasing out the milk quota system" 8.12.2010 COM(2010) 727 final.

measures to be non-discriminatory and not more trade-restrictive than required to achieve a legitimate objective. Measures should not create unnecessary obstacles to international trade.

b) Cloning activity in third countries

As commercial cloning for food production is presently taking place in third countries and as the EU imports animals, reproductive material and food, which could potentially be clones or derive from clones, the third country trade aspect of this policy must be taken into account. Based on the replies to the questionnaire (see Section 1.2. above), third countries' authorities do not have any information about the number of clones and the specific activities carried out by cloning companies on their territory, or about the amount of food products of clones or progeny of clones. Based on the consultant's study and information received from US companies and stakeholders (Annex II), cloning takes place primarily for bovine (for food production) and equine (for elite sports horses). It is also carried out for porcine (for food production) but to a much lesser extent. It is presently not known whether it is used commercially for ovine species and should have just started for caprine in the US. The possible reasons for this relatively limited development could be due to the low efficiency of the technique as highlighted by EFSA and the related high costs, placing prices of clones above the prices of high quality animals. This could also explain why cloning could represent a higher commercial interest in the case of more expensive animals such as bovine for breeding purposes or horses for sport purposes.

The overview of commercial cloning is summarised below:

Overview of commercial cloning in third countries

Bovine animals: the most developed. Applied to cattle in the US, Canada, Argentina and Australia[43] It may also be undertaken in Brazil, New Zealand, Chile, China and Uruguay based on the presence of cattle cloning companies in these countries.

Milk and meat from the offspring or descendants of cloned bovine animals have entered the food chain in the US and may have done so in Argentina; these are the products most likely to continue to enter human food chains in the near future. The Swiss government says that 'several hundred' second or third generation descendants of clones are in Switzerland (of a total 1.5 million head of cattle);[44]

Porcine animals: consultations with the US cloning industry suggests that there is some commercial cloning for pigs in that country and that it is becoming more common. It may also be undertaken in New Zealand and China based on the presence of pig cloning companies in these countries.

Ovine and caprine animals: consultations with industry stakeholders in the EU of third country Competent Authorities indicate that commercial cloning of ovine or caprine animals outside the EU is uncommon. Some commercial cloning of these animals has started in the US, but at very small scale. **Equine animals**: consultations of third country Competent Authorities indicate that there is no livestock cloning activity currently being conducted for equine animals. Sport cloning is undertaken in North and South America and Brazil and South Korea.[45]

Source GHK study page 26

[43] DG SANCO survey to Member States and third countries regarding cloning activity, 2012.

[44] Kanter, J. (2010) 'Cloned Livestock Gain a Foothold in Europe', New York Times, July 29, 2010, available from: http://www.nytimes.com/2010/07/30/business/global/30cloning.html?pagewanted=all.

[45] Carroll, R. (2011) 'Argentinian polo readies itself for attack of the clones: Player forms alliance with genetics laboratory to clone equine champions in hope of replicating performance', The Guardian, http://www.guardian.co.uk/world/2011/jun/05/argentinian-polo-clones-player, 2011

c) EU imports of live animals, reproductive material and food of animal origin

The EU imports live animals (LA), reproductive material (RM) and animal products, in many cases from one or more of the five countries (USA, Canada, Argentina, Brazil, Australia) where commercial cloning is taking place. The extent to which these imports are related to clones, to the reproductive material of clones or their progeny is presently unknown as there is no requirement (neither under EU law; nor in third countries) to identify them as such.

As shown in the table 1 below, the share of imports of live animals and of reproductive material compared to EU production or livestock is very low (respectively <0.01% of EU livestock and 2.5 % of EU use of reproductive material). The share of EU imports of meat and milk products is also low except for ovine /caprine and equine meat, where it ranges between 20 % and 50 % of EU production respectively.

For these species, however cloning is not taking place for food production or may have started to a very limited extent.

Table 1 Summary of EU imports from main exporting countries

	Species	**Main exporting country**	**Amount**	**% of EU imports of livestock, use or production**
Live animals	Bovine	Canada and New Zealand	Very low	<0,01 % of livestock
	Pigs	Russian federation, Canada and USA	Very low	<0,01 % of livestock
	Others	USA, Argentina, New Zealand and Chile	Very low	<0,1 % of livestock
Reproductive material (semen)	Bovine	USA, Canada, New Zealand and Australia	Low at EU level *but* medium to high in some MS	2.5 % of use of semen in EU in average and up to 20 % or more in certain MS *
	Others	Canada, USA, Australia and New Zealand	Not available	Not available
Reproductive material (embryo)	Bovine	Canada and USA	Not available	Not available
Meat	Bovine	Argentina, Brazil and Uruguay (70 % of all imports), Australia, USA, New Zealand	Low	EU net importer (5 % of EU production)
	Ovine	New Zealand (80 % of all imports)	High	EU net importer (23 % of EU production)
	Caprine			
	Porcine	Chile, USA and Australia	Very low	EU self-sufficient (<0.1% of EU production)
	Equine	Canada, Argentina, Mexico, Uruguay	High	EU net importer (50 % of EU production)
Fresh milk	Bovine Caprine Ovine	Croatia, Switzerland and Norway (99 % of all imports)	Very low	0.01% of EU production
Cheese & butter	Bovine Caprine Ovine	Switzerland, New Zealand, USA, Australia and Norway	Low	2 % of EU production

Very low: <1%; low: 1% - 5%; medium: 6% -20% high: 21% -50%;

*Sources: Eurostat External Trade Statistics (COMEXT), Traces; * Source: Commission report on animal cloning for food production–COM (2010) 585 and stakeholders in Advisory group meetings (minutes in Annex II).*

However, in terms of value, as shown in table 2 below, out of a total value of 3.6 billion € of imports of food per year, imports of meat accounts for 80 %, of which the highest share is composed of bovine meat (60 %) imported from countries where cloning takes (notably USA, Argentina, Brazil). The share of ovine and caprine meat in value of all meat imports is also relatively high (35 %) but as stated above, cloning for these species is not developed for the time being.

EU trade on reproductive material takes primarily place with the USA and Canada.

- *Imports* of reproductive material account for a small percentage of total use in the EU (2.5% on average[46]) but the breeding sector considers access to this genetic material as essential to the continued viability of the industry[47]. The majority of imported reproductive material is from bovine (in value): for example in 2011, the value of all imported reproductive material (all species) was of €48 million in 2011, originating at 93% from bovine. The US and Canada are very dominant in EU supply of reproductive material for all species (bovine at 98%, porcine at 100%, ovine and caprine at 80 %, equine at 98%).

-The *EU exports* bovine semen worth €25 million each year[48] of which almost half to the US, Canada and Latin America.

Table 2 Import value in million € from 2010 to 2012

	Species	2010	2011	2012
Live animals	**TOTAL Live animals**	**193**	**120**	**185**
	Bovine	0.91	1	0.62
	Swine	1	0.53	0.77
	Sheep and goats	0.28	0.85	0.12
	Equidae	191	118	184
Meat	**TOTAL Meat**	**2731**	**3046**	**2847**
	Bovine	1576	1702	1693
	Porcine	58	55	52
	Ovine/caprine	999	1195	1003
	Equine	98	94	99
RM*	**TOTAL**	**45**	**48**	**49**
Milk &Milk products**	**TOTAL**	644	688	722
TOTAL		**3612**	**3901**	**3802**

** Reproductive Material from bovine ** from bovine, caprine, ovine*
Source: Eurostat. Comext -Extracted 7/06/2013

2.7. Does the EU have the right to act (subsidiarity)?

Right to act (EU competence)

Article 13 TFEU specifies that welfare requirements of animals shall be taken into account by the Union and the Member States when formulating and implementing Union

[46] There are no statistics on EU use of reproductive material; the share of imports is therefore based on estimates – source : Commission report of 2010
[47] ICF GHK report 2012
[48] Figures based on 2006-2011 COMEXT data

policies. However, this Article in itself does not grant the EU a competence to legislate on animal welfare.

Existing Union legislation on both animal welfare and identification of farm animals and their reproductive materials is based on Article 43 TFEU (Agriculture). Measures regulating the use of the cloning technique would address the associated animal health and welfare concerns, and would prevent the development of diverging national legislation on this technique adopted to implement the general principles laid down in Directive 98/58/EC on the protection of animals kept for farming purposes and the consequent disruptions of the concerned agricultural markets. They would therefore ensure legal certainty and a level playing field for breeders and farmers and to ensure uniform conditions of production for farmers. Therefore, it may be possible to base certain measures on Article 43 TFEU.

As regards the EU competence under Article 114 TFEU (Internal Market), this requires a risk of divergence between national legislations as explained in paragraph 2.3 above.

Finally, EU competence for certain measures could be drawn from Article 352 TFEU (*Flexibility Clause*) under the conditions set out therein.

Necessity of the EU to act (Subsidiarity)

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 food 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.

Proportionality

The options identified as feasible as a result of this impact assessment should be suitable and necessary to achieve the objectives set out below and they should present the best cost benefit ratio to resolve the issues at stake, as explained in the comparison of options in chapter 6.2.

3. OBJECTIVES

3.1. General objective

To address concerns raised as regards cloning for farm purposes and ensure uniform conditions for farmers in the EU and to protect consumer interests as regard food from cloned animals.

3.2. Specific objectives

Objective 1:

To ensure uniform conditions of production of farmers in the EU while protecting health and welfare of farmed animals;

Objective 2:

To protect consumer interests as regards food from cloned animals

Objective 3:

To safeguard the competitiveness of farmers, breeders and food businesses in the EU.

3.3. Consistency with other EU policies and horizontal objectives

The objectives identified are in particular in line with:

- the *Europe 2020 Strategy* in favour of a sustainable development based on innovation and competitiveness of EU economy and agriculture;
- the *Common Agricultural Policy* objectives including in relation to the rearing of animals for food production;
- the *EU Food Law* defines the requirements applicable to all foods as regards food safety and consumer information.

It also improves coherence with other EU policies notably on:

- the *Novel Food Regulation*, which as mentioned in 2.6.1.a. above, addresses only food from clones;
- the *Animal welfare strategy for the protection and welfare of animals for 2012-2015*[49], which in addition to the Directive 98/58/EC (see 2.6.1 above), aims to further improve the welfare of animals in the European Union;
- the *EU legislation on Food Information to Consumers*[50] which lays down labelling requirements applicable to all foods.

Finally, it takes into consideration the impacts of this initiative on the *Charter of Fundamental Rights of the European Union* especially as regards the freedom to conduct a business (Article 16) and consumer protection (Article 38) as further analysed in section 6.2.

4. POLICY OPTIONS

4.1. Policy options included in the analysis

In light of the problems and objectives outlined above, 4 options were retained. They are described below and are also summarised in Table 3 (below).

Option 1: no policy change. The pre-market approval for food from clones under the current Novel Food Regulation would be maintained. Regarding cloning, Member States would continue to be entitled to act at national level, in line with Directive 98/58/EC on animal welfare.

Option 2: Pre-market approval of food from clones, from offspring and descendants.

As regards food from clones, this option differs from the status quo from a procedural point of view only[51].

The main difference to option 1 is that it would enlarge the scope of the pre-market approval from food of clones to food of offspring and descendants of clones.

[49] Communication on the European Union Strategy for the Protection and Welfare of Animals 2012-2015 COM(2012) 6 final/2.
http://ec.europa.eu/food/animal/welfare/actionplan/docs/aw_strategy_19012012_en.pdf

[50] 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.

[51] Under this option, a streamlined and centralised approval process would be introduced which would involve the Commission and EFSA

Accordingly this food would become subject to a scientific risk assessment by EFSA followed by a decision of the Commission to authorise or not the food[52].

It has to be stressed that EFSA has already confirmed the absence of a risk to food safety.

However, it is important to assess this policy option since this option had been put forward by the co-legislators during the discussions between 2008 and 2011 on a reform of the Novel Food Regulation. Moreover, EFSA could not establish the absence of food safety concerns for the other species than porcine and bovine (ovine, caprine, equine) in the absence of specific data. Therefore the pre-market approval would be useful (i) to confirm the safety for the bovine and porcine species; and (ii) to encourage the establishment of data for the other species so as to be able confirm in a second stage their safety.

Option 3: labelling of food from clones, offspring and descendants

Sub-option 1: labelling of food from clones

Sub-option 2: labelling of food from offspring

Sub-option 3: labelling of food from descendants

Under this option food from clones, offspring and descendants would be labelled. The labelling would apply incrementally to the various generations analysed in the two sub-options or only to one of them according to the results of the analysis.

In order to be able to label this food, traceability systems would need to be in place for the live animals (as regards previous generations of animals), reproductive material and the food from the animal (as regards the individual animal which was the source of the food).

Sub-option 4: voluntary labelling

Sub-option 5: mandatory labelling

Under this option the possibility to introduce voluntary labelling (sub-option 4) or mandatory labelling (sub-option 5) will be investigated as well as the different type of food covered: direct fresh food (fresh meat or fresh milk or both) or all types of food (fresh food and processed food such as sausages, cheese, etc.).

Overall, this option differs from the status quo as it does not require a pre-market approval and extends the labelling to food from offspring and descendants.

Option 4: temporary suspension of the technique and of imports of live clones, their reproductive material and their food.

Under this option the use of the cloning technique would be suspended in the EU until this reproduction technique has been developed further so that the welfare issues are alleviated. As a consequence, no clones, reproductive material and food from clones would be produced on the EU territory.

To avoid circumvention of the suspension of the technique in the EU and create uniform conditions of production for breeders and farmers, imports of the "*results*" of the use of

[52] Streamlined procedure was already foreseen in the original Commission proposal of 2008 (referred to in Section 1.1 above)

the technique in third countries (live clones, their reproductive material and their food) would be suspended as long as the technique is suspended in the EU. As a result, no offspring of clones would be produced in the EU.

This option differs from the status quo as it forbids explicitly cloning on a temporary basis throughout the EU whereas the rules in place (i.e. Directive 98/58/EC) require Member States to act at national level in a more general manner (i.e. "*to avoid unnecessary pain, suffering or injury*" (…) including in the "*context of the breeding technique*").

In addition this option includes explicitly the suspension of the use of the clones (i.e. suspension of the import of reproductive material and food of clones).

Table 3. Summary of the description of options:

Option	**Description**	**Generation covered**	**Traceability to implement the option**
No Policy change	- PMA (+ labelling of the food on a case by case basis) - Directive 98/58/EC (animal welfare)	Clones	- For PMA live clones + their food (in EU and third countries exporting to EU) ; - For animal welfare, none
Pre-market approval	PMA	Clones, Offspring and Descendants	Traceability of live clones, offspring and descendants, + reproductive material & food of clones (in EU and third countries exporting to EU)
Labelling of food	Labelling of food – voluntary or mandatory (fresh meat or fresh milk or all type of food)	Clones, Offspring, Descendants	
Suspension	Suspension of : cloning technique in EU + imports of clones + reproductive material & food of clones	Clones	Traceability of clones + their food + their reproductive material (in third countries)

4.2. Options discarded at an early stage

The preliminary options below have been discarded after discussion in the IASG based on the following criteria: i) the *legal feasibility* of the proposed options (in light of TFEU, EU secondary legislation and WTO); ii) *the technical limitations.*

(i) A permanent ban of the cloning technique, clones and their use (reproductive material and food) was discarded as the underlying animal health and welfare concerns identified by EFSA are linked to the present scientific and technological development of the cloning technique. The latter may, however, mature and thereby alleviate partially or fully the concerns: the prohibition linked to the use of the technique and of the clones needs therefore to be temporary with a review clause. A permanent ban would be unjustified and disproportionate.

(ii) A permanent ban or **temporary suspension of food from offspring and descendants** was discarded as in the light of the EFSA opinion there is no scientific concern or food safety reason to forbid - whether temporarily or permanently - market access for such food. There is therefore no legal basis to act for this option.

(iii) The option of setting up harmonised conditions of use of the cloning technique for food production was discarded based on the EFSA opinion: under current scientific knowledge, it is not possible to define any conditions of use of the technique which would alleviate animal health and welfare concerns identified by EFSA. It is therefore not possible to define technical parameters to this end.

(iv) Measures to improve consumer awareness that would potentially alleviate the consumer concerns or to upgrade voluntary labelling schemes have also been discarded for the following reasons:

a) consumers who reject the technique for ethical reasons, would not accept it more if the technique is explained better and in further detail;

b) as long as the technique, even explained better, implies the suffering of clones and surrogate mothers, the reticence of consumers would remain unchanged;

c) informing consumers that offspring and descendants are produced with traditional breeding techniques and that no particular welfare concerns can be associated with this, could clarify the difference between clones and offspring. It would however not alleviate the reticence of consumers towards cloning in the absence of measures on clones and the cloning technique;

d) it is difficult to establish a link between cloning and benefits to consumers. Clones are of interest in high productivity farms where "elite" animals are already used. Links between cloning and positive effects on consumers (such as lower prices or contribution to agricultural landscape) may therefore be difficult to establish;

e) information campaigns on such issues could be carried out by the food sector and not necessarily by public authorities whether at national or EU level;

(v) Upgrade of labelling schemes: existing specific labelling schemes (whether organic or other similar quality labelling schemes) do not exclude the production of food from offspring of animal clones. This is because offspring is produced with traditional breeding techniques and does not therefore deserve or require special treatment. Based on the information available, no FBO has so far set up any voluntary labelling scheme on the non-cloning origin of animals. In cases where FBO could guarantee non-cloning origin of animals the food is obtained from specific breeds produced exclusively locally (not cloned or obtained from reproductive material of clones). This is presumably because the other positive messages have a better impact on consumer behaviour. If there would be an interest to bring out products of non-cloning origin, it would have to be in combination with other positive messages - such as organic, GM free, special consideration of welfare of animals concerns etc.

5. ANALYSIS OF IMPACTS

The analysis has been performed using data provided by the external contractor ICF-GHK and gathered through other data sources available[53]. However, limited quantitative data have not allowed for a detailed quantitative analysis.

5.1. Option 1: No policy change

5.1.1. Description of the option

Food from clones would remain within the scope of the Novel Food Regulation and subject to a pre-market approval (PMA) based on a food safety assessment. As described

[53] Stakeholder consultations in meetings of Advisory Group on the Food Chain and bilateral meetings.

in section 2.6.1. paragraph b), the FBO's need to submit an authorisation application to the Member State's authority to perform a scientific risk assessment and pay fees for this. In case of objections by other Member States to the risk assessment, the file is sent to the Commission who consults EFSA who performs a new risk assessment on the basis of which the Commission adopts a Decision for authorisation or not. If an authorisation were requested and then granted, clones would need to be traced. At present this traceability system does not exist. In addition, labelling (as "derived from clones") could be requested on a case by case basis.

Food from offspring and from descendants would continue to be marketed without any distinction as to the animals it is obtained from. This food is not covered by this option, consumers would not be able to know if the product they are purchasing is deriving from offspring and/or descendants

The use of the cloning technique would continue to be regulated by Directive 98/58/EC. Where Member States fail to implement the Directive in relation to cloning, the Commission could start infringement procedures. If Member States would take measures specific to cloning to comply with the relevant requirements of that Directive, such measures would not necessarily be uniform and could apply, for example, to different species or types of breeds, to the technique as such or also to the imports of lives clones and their products. Different national approaches might disturb the functioning of the concerned agricultural markets.

As EFSA has already identified animal health and welfare issues linked to the use of the cloning technique, the future use of welfare indicators, which could be developed in the context of the Animal Welfare Strategy (see section 2.6.1., paragraph a) above) would not affect the status of this issue.

5.1.2. Economic Impacts

Regarding the pre-market of food from clones, the potential economic impact relates to food business operators (FBOs) which would like to market food from clones in the EU. The FBO will have to file an authorisation application to be submitted to the national competent authority who would charge fees to FBOs[54]. Where a fee is in place, it ranges from EUR 830 to EUR 25 000 and from EUR 900 to EUR 2 000 for a simplified procedure.

FBOs bear a series of additional costs related to the preparation of the file and the application procedure. In detail, the cost of filing an application under the Novel Food Regulation has been estimated to be up to 400.000 €[55] when toxicological tests are required (see details in table 4 below). Where the file is referred to EFSA for an opinion, there is additional EU budget needed to finance the costs borne by EFSA in processing applications, evaluated around 83 000 € per application for Novel Food[56]. Under the current Novel Food Regulation, authorisations are individual: each FBO who intends to put food from clones on the EU market would require a pre-market approval for the products; subsequent operators who wish to put similar products to those already authorised on the market would need to get approval from their national authorities for

[54] Fees perceived by Member State agencies to make the scientific risk assessment under Novel Food Regulation.

[55] Estimation done by assuming the equivalence with the costs of filing an application under Novel food Regulation. Source: *Impact assessment on Revision of Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety on the establishment of fees for EFSA.*

[56] Source : EFSA impact assessment, Annexes page 56

"substantial equivalence", which, if granted, would not imply a new application dossier and risk assessment.

Table 4: Costs linked to applications dossiers for pre-market approval

Cost	Action
from 20.000 € to 45.000 €	to set up an application file for risk assessment
around 300 000 €	**only if toxicological tests are required**
administrative fees from 800 to 25 000 €	for the risk assessment by Member State

In addition to above application costs, FBOs would be obliged to adapt their traceability system to trace food from clones and could also be requested to label their food. Farmers and breeders would need to trace the clones. The additional costs are not significant:

- in view of the rather limited number of animals concerned and the likelihood that they would be processed apart and labelled through a *segregated food supply chain** (see Section 5.3.2. paragraph b) below), the traceability cost of food from clones for all EU operators along the food chain would be negligible[57] and the amount of food produced in this way limited;
- costs for tracing clones by farmers and breeders are also considered marginal (see Section 5.3.2.b paragraph b) below);
- the average cost at company level for a small label change has been estimated at €2,000-4,000; a full label redesign has been estimated at €7,000-9,000 (or €9,000-13,000 in total). It should be noted that most companies (~80%) redesign their label every three years as a normal part of their business operation[58] (see section 5.3.2 paragraph c).

European associations[59] representing the food industry, the milk and meat sectors are in favour of this option, i.e. maintain the principle of a pre-market approval for food of clones only (see Annex III.3).

As regards the "no policy change" on cloning and taking into consideration the very limited cloning activity in the EU, the economic impact on production costs for EU breeders, farmers and on third country trade is considered non-significant. This is mainly linked to the low economic profitability of the cloning technique which has an efficiency rate[60] according to EFSA (calculated as the number of live offspring as a proportion of the number of transferred embryos) still in the range of 6-15% for cattle and of 6% for pigs, albeit occasionally higher success rates were reported. Farmers and breeders would be able to continue to import live clones or their reproductive material from third countries where commercial cloning takes place.

Regarding SMEs, the specific impact mainly arises from the costs for having to recruit specialists not permanently available in FBOs themselves to prepare the applications. Another issue, which could present particular challenges for micro and small enterprises -including direct on-farm sales of food of animal origin to the final consumer- stems

[57] Source ICF-GHK study on animal cloning December 2012.
[46] Source Impact Assessment Report on general food labelling issues 30/01/2008, SEC (2008) 92
[59] EDA (European Dairy Association); Eucolait (European Association of Dairy Trade); UECBV (European Livestock and Meat Trade Union); CLITRAVI (liaison Centre for the Meat processing industry in the EU); Food and Drink Europe.
[60] According to EFSA, if the comparator for cattle cloning is in vitro fertilisation (IVF), the background (i.e. the percentage of live offspring per transferred embryo from IVF) is 45-60%. Compared to this efficiency of IVF, the efficiency of cloning can be estimated at 13-25%.

from the rules on traceability and labelling, where the lack of economies of scale (lowering the cost per unit) may lead to higher relative costs for SMEs.

As far as third countries are concerned, in case their food industry would intend to put food from clones on the EU market, exporters would need to file an application for authorisation to EFSA. They would have to incur the same application costs of the EU business operator as well as additional labelling and traceability costs. If no authorisation is granted[61], food industry in third countries where cloning technique is used, would have to either remove food of clones from their food chain or remove it from the food exported to the EU. The clones would need to be identified and registered as such if their food is to be authorised by the EU before being exported.

Apart from food from clones which needs to be identified, no other impact under this option is expected on third countries: they would continue to be able to export live animals (clones and progeny), their reproductive material and their food.

5.1.3. Impacts on consumer protection

The impact of the *pre-market approval of food from clones* on consumer protection is considered positive: in case labelling is requested upon authorisation, consumers would be able to identify the food derived from clones and to make informed choices as to whether a food product contains or not products derived from clones. More than 70% of the total respondents to the IPM public consultations are in favour of a mandatory labelling of food not only from clones, but also from offspring and descendants of clones.

This approach is also supported by the European consumer association (BEUC)[62]. In its comments BEUC urges the Commission to set up: "*a full compulsory traceability system (which includes clones and their offspring)*".

The retail sector (Euro Commerce) confirms that they would sell the products according to acceptance by consumers but "practical solutions" would need to be found to ensure traceability (Annex III paragraph 3).

However, this option does not entirely respond to consumer expectations as information of food from offspring and descendants would not be provided.

5.1.4. Impacts on food prices and employment

In case the authorisation of *food from clones* would impose labelling, some price-effects could be expected due to the additional costs for ensuring traceability of clones and food obtained thereof. However, as explained in Section 5.3.2. paragraph c) below, the impact is expected to be low although it is not possible to quantify it.. Moreover it is not possible to quantify the effect on employment for lack of data.

Regarding the prices for *food from offspring and descendants*, they would remain unchanged, as no system is set up to ensure the expected information is available to consumers and therefore no impact on employment resulting from labelling and traceability requirements is expected.

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[61] Which is the case at present.

[62] Cloning for food production - BEUC comments on the European Commission report at http://www.beuc.org/Content/Default.asp?PageID=2139

5.1.5. Impact on Animal Welfare

Under this option animal welfare problems are addressed by the Member States under the Directive 98/58/EC.

5.2. Option 2: Pre-market approval for food from clones, offspring and descendants

5.2.1. Description of the option

Under this option FBOs would have to file an application for authorisation to market food derived from clones, offspring and descendants. Contrary to option 1, the authorisation would be submitted directly to the Commission who consults EFSA for an opinion, avoiding thereby that FBOs have first to go to Member States' authorities for a first assessment. This streamlined centralised procedure was already foreseen in the 2008 Novel Food proposal as described in Annex VI paragraph 5. In addition, under this option, the scientific assessment would cover food from offspring and descendants, although not considered as being "novel" (as derived from conventionally bred animals) and presenting no safety issue as indicated by EFSA.

This option would be more efficient than option 1, by imposing a centralised authorisation system based on a risk assessment.. Yet this option does not address directly the specific objectives set out in Section 3.2. However, it has been considered worthwhile analysing it as it was supported - for food from clones and offspring(1st generation) - by unanimity by the Council in first reading during the inter-institutional discussions on the Novel Food proposal (referred to in paragraph 1.1. above). As the offspring and the following generations present exactly the same characteristics[63], it is appropriate for sake of coherence and completeness that this option also includes food from descendants of clones. This option could be considered appropriate for food from clones because of their novelty aspect and because this option provides a more efficient approval system than under option 1. However, as regards food from offspring and descendants this option is inappropriate in the absence of any specific food safety issue as highlighted by EFSA.

Under this option, an application for authorisation would need to be submitted by EU or third country FBOs, and authorisations would be granted based on a risk assessment. In order to do so an underlying traceability system would need to be in place. At present this traceability system does not exist. The implementation of this option implies that in the absence of authorisation, the food could no longer be put on the EU market.

This approach is also supported by the European consumer association (BEUC)[64]. In its comments BEUC urges the Commission to set up: "*a suitable risk assessment and authorisation procedure complemented by a compulsory labelling system for food derived from clones and their offspring, should the temporary suspension be lifted in the future*".

[63] In terms of (i) not presenting any novelty aspect justifying their inclusion in a Novel Food Regulation and of (ii) not raising food safety concerns as indicated by EFSA.

[64] Cloning for food production - BEUC comments on the European Commission report at http://www.beuc.org/Content/Default.asp?PageID=2139

Conversely, industry representatives[65] are against taking measures beyond food of clones, as there is no food safety concern with food from offspring and descendants. They base themselves mostly on the EFSA opinion of 2008 and subsequent statements.

5.2.2. Economic Impacts

As regards the EU, the expected economic impact of this option touches overall the same aspects of the assessment performed for food from clones under option 1. However the magnitude of the impact is considered more important as this option covers a longer chain and entails additional impacts: the offspring and descendants of one single animal increases exponentially by thousands of animals per generation (see Annex XIII paragraph 2).

The costs for filing an application for pre-market authorisation are the same than those detailed in section 5.1.2 except for the fees paid at national level which will no longer exist. In the case of an individual authorisation as under current Novel Food Regulation (option 1), agreement on *substantial equivalence* for each FBO is required. In the case of a generic authorisation, a single FBO would bear the costs of application for a given food while all other operators would benefit from this authorisation.

All FBOs –whatever the type of authorisation foreseen- would have to be able to identify this food as stemming from offspring or descendants of clones to be able to prove that it has been approved beforehand. The impact for traceability would be high for the EU food industry as the number of animals concerned (offspring and descendants) would be much extended (as compared to clones).

FBOs would need to adapt their traceability system to trace food from the respective animals. There would therefore be costs for (i) the traceability of food for all EU operators along the food chain, which would be important in view of the very high number of animals concerned; and for (ii) the identification and registration of clones, of offspring and descendants (and of their reproductive material). The cost of traceability of animals and of food are described in further detail in Section 5.3.2. below.

Under this option, EFSA would have to perform a risk assessment on food from offspring and descendants of clones not considered at risk for public health. There would in addition be cost to be borne by the EU budget to cover the costs involved in processing applications (estimated at 83000 € per application) for Novel Food[66].

Such assessment is only appropriate when possible risks are identified. In the case of food from clones, offspring and descendants of clones, EFSA did not consider them different from other food. The only justification for an authorisation could be applied to food from clones, as here the animal is produced with a "novel" reproduction technique; for other food such pre-market approval would be even less justified from a scientific point of view.

SME's cannot be excluded from any of the PMA mentioned above. This option has therefore potential to impact SME profit margins and thus growth in particular as they do not benefit from efficient production systems and/or economies of scale enjoyed by

[65] Food Drink Europe; British Agricultural Bureau, the European Forum of Farm Animal Breeders (EFFAB); the European Dairy Association (EDA); and European Association of Dairy Trade (Eucolait); European farmers /cooperatives (Copa Cogeca).

[66] Source : EFSA IA annexes page 56

larger firms. Traceability of food could present particular challenges for micro and small enterprises but there may be some differences among Member States (see Annex X)

*As regards third countries***,** the PMA requirement for food from offspring or descendants would create major difficulties for EU importers and their third country suppliers. EU importers need to have the guarantee that either (i) imported food does not derive from offspring or descendants, or (ii) imported food has been approved. Otherwise, they would no longer be able to maintain these imports. As explained in Section 5.3.3. below, third country operators would need to identify the food and therefore the animals concerned (clones, offspring and descendants of clones) which is not the case at present. Imports could be reduced or halted because third countries would be unwilling or unable to meet the requirements of the EU legislation. This would have an impact on EU imports of meat, milk and other food products accounting[67] today for around 1.7 billion € for beef, 1 billion € for sheep and goat meat and 722 million € for milk products[68] and could lead to major trade disruptions.

5.2.3. Impacts on consumer protection

Under this option, consumers would be reassured that the food is safe but still, it would not allow consumers to identify food from clones, offspring or descendants and make informed choices. For this to happen, mandatory labelling, as described in Option 3 below, would need to be provided for.

5.2.4. Impact on prices and employment

There would be a negative impact on food prices as the price of meat and milk and derived products could increase to compensate for additional compliance costs due to extended requirements. The negative impact on consumer markets (prices and choice) would be even higher if the major import, such in beef, would cease. It is however not possible to quantify the envisaged impact as no data is available, nor is it possible to quantify the effect on employment.

5.2.5. Impact on Animal Welfare

Under this option animal welfare problems are not addressed.

5.3. Option 3: labelling of food from clones, offspring and descendants

5.3.1. Description of the option

As set out above (section 4.1), this option has two elements: the scope of the labelling, and its modalities (obligatory or voluntary)

(i) *In terms of scope*, this option covers the labelling of food of clones, offspring and descendants. The following two sub-options have been identified:

- Sub-option 1: labelling of food from clones

- Sub-option 2: labelling of food from offspring

[67] Sources Eurostat 2012

[68] Source ICF-GHK study on animal cloning December 2012, page 18

- Sub-option 3: labelling of food from descendants

Labelling of food as stemming from these animals is not a self-standing option. Whether such labelling is voluntary or compulsory, it is subject to two main conditions: (i) the identification and traceability of animals and their reproductive material (RM), and (ii) the traceability of the food. These two requirements imply costs in addition to the cost of labelling as such as described in paragraphs 5.3.2. to 5.3.3. below.

(ii) *In terms of modality of labelling*, the following two options have been identified:

- sub-option 4: voluntary labelling

- sub-option 5: compulsory labelling.

The modality of labelling is particularly relevant for consumer protection and is assessed in further detail under paragraph 5.3.4. The *voluntary* labelling could be of interest to FBOs when it represents an added value for selling their products, which would enable them to cover extra costs. It would be put in place by some FBOs depending on market demand. The *mandatory* labelling implies that costs are borne by all FBOs, who have to check whether the food derives from clones, offspring and/or descendants.

The requirements increase exponentially with the generations as shown in table 5 below:

Table 5 Conditions of identification/ traceability to be fulfilled to label food from clones, offspring and descendants of clones

Food from :		**CONDITIONS OF IDENTIFICATION/TRACEABILITY**												
		CLONES			**OFFSPRING 1st generation**			**DESCENDANTS**						
								2nd generation			**3rd generation**			**etc.**
		Food	LA	RM	Food	LA	RM	Food	LA	RM	Food	LA	RM	
Clones		X	X											
Offspring			X	X	X	X								
Descendants	***2nd generation***		X	X		X	X	X	X					
	3rd generation		X	X		X	X		X	X	X	X		
	4th etc.													

LA : live animals ; RM reproductive material

5.3.2. Economic impacts in EU - costs

Labelling requires confidence that its content is correct. To provide the information as to whether food was obtained from clones, their offspring or their descendants on the label, it is necessary to create a documented link between a food and the animal/animal clone.

This requires that parentage information for every food producing animal is conveyed through the food production chain. This becomes more costly with every generation between the clone and the animal, reproductive material and the food.

As explained above (section 2.6.1.) current legislation on traceability does not conserve the require link between an individual animal and the food obtain thereof throughout the food production chain. It does not ensure the link between the animal and its parents throughout all stages of livestock production. As a result to label food derived from

clones, their offspring or their descendants, production processes would have to be profoundly amended to ensure such link.

It is obvious that, depending on the sub-option chosen, costs can vary substantially. This was also highlighted in the consultations, where industry representatives expressed themselves against labelling of food from offspring and descendants (as highlighted in Annex II and Annex III paragraph 3) and underlined the risk of trade disruption. Representatives of European farmers/cooperative associations[69] consider that traceability extended to offspring puts an administrative burden on operators at all levels of the supply chain.

a) Sub-option 1: food from clones

While no precise numbers exist, it can be presumed that few animals will be cloned as the conventional breeding techniques will remain mainstream and the cloning one ancillary. Evidence indicates that productivity increases resulting from use of cloning technique as currently performed are marginal.

There is thus little economic incentive to use it. As a result the technique would not be used for food production in the EU up to 2020. Moreover, as set out above, the clone itself does usually not serve as source for food.

The consultant[70] thus presumed that if these assumptions are correct the clones in circulation would be so few and that they could be closely traced with limited efforts. The consultant could, however, not demonstrate that this is really the case.

b) Sub-options 2 and 3 - Cost of traceability of food of offspring and descendants

To the contrary of clones, the traceability of food from offspring and descendants implies a higher number of conditions (see Table 5), which increase exponentially per generation and which need to be fulfilled.

In particular, both farmers and breeding companies have to adapt their registration and traceability systems and to introduce the information related to the status of their offspring or descendants and their reproductive material (see (i) below).

Moreover, a traceability system would have to be set up which links every piece of meat, and every litre of milk to a specific animal. Due to the complexity of such system, the multitude of actors involved and the uncertainties surrounding the functioning of existing systems costs could not be calculated. However, surely, they come at a cost (see ii below).

(i) Traceability at the level of farmers and breeders

The costs for adapting traceability systems of animals and their reproductive material have been calculated by the consultant[71] on the basis of costs per operator (working time[72] and investments).

[69] European association of farmers /cooperatives (Copa Cogeca).
[70] IFC GHK 2012
[71] IFC GHK 2012
[72] The working time necessary as a minimum to learn the new legal requirements and define what is necessary to record the new information has been estimated at one hour per farm. For breeding companies

They were divided into: i) one-off learning costs to familiarise with new requirements; ii) one-off investments in equipment; iii) annual operating costs for recording information on status and parentage ; and iv) annual reporting and inspection costs to respond to information requests from customers and control authorities.

As shown in Table 6 below, the costs for farmers have been qualitatively assessed and considered marginal. The costs for breeding companies (importers and established in the EU) as well as importers of live animals would be low: the one off costs per operator range between 3 000 € and 3 600 € and the annual costs per operator around 100 €.

These costs should be, in principle, relatively limited as EU operators have already the obligation to introduce information on all animals in systems in place in the EU (see Section 2.6.1. above). In practice, the cost is most likely to be higher because of the number of animals concerned.

Table 6: Cost of traceability for offspring and descendants and their reproductive material (RM)

in €		EU farmers	Live animals	Breeding companies	
			EU Importers	EU Importers	EU Producers
Number of operators		Over 7 million	22	69	215
Learning	Learning all operators	Marginal	71 000	251 000	783 000
	Per operator	Marginal	3 227	3 637	3 641
Compliance	Investments in equipment	Minor modifications to existing systems	Not available		
	Operating costs	Marginal	Marginal		
Reporting & inspection	all operators	Marginal	2000	8 000	22 000
	per operator	Marginal	90	116	102

** Source ICF GHK study tables 8.6, 8.7 and 8.8.*

ii) traceability of food and link with the individual animal

Operators would need - throughout their operations - to be able to recognise whether every food is derived or not from progeny of clones. This would require a detailed and sophisticated (probably electronic) traceability system. Without such a system, linking the food of progeny (over generations) to the animal clone is unworkable[73]. The setting up and implementation of such a system would produce require major investments and maintenance costs that the consultant was unable to estimate as shown in Table 7 below.

this time has been estimated at 70 hours per company. The minimum time necessary on a yearly basis to record the data and report it has been estimated at 2 hours per operator. Source : ICF-GHK Study

[73] As explained in Section 5.5. there is no physical difference between food from clones, food from their progeny and food from other animals.

Table 7: cost of traceability of food of offspring and descendants in non-segregated food supply chains

In €		Slaughterhouse / markets/ assembly centres	Importers food	Food processors/ manufacturers	Wholesalers	Retailers
Number of operators		15 491 (bovine only)	715	81 993 (all species)	82 801 (all species)	623 812 (all species)
Learning	**All operators**	713 000	30 000	3 772 000	No data	No data
	Per operator	46	43	46	No data	No data
Compliance (invest-ments and operating costs)	Unfeasible – no quantitative data					
Reporting and inspection	**All operators**	1 426 000	6 000	7 544 000	Marginal	Marginal
	Per operator	92	8	92	Marginal	Marginal

Source ICF GHK study tables 8.6, 8.7 and 8.8.

The consultant argued that these costs would be avoided in food supply chains if all actors involved (farmers, slaughterhouses, cutting plants, traders, etc.) "segregate" between "clone/progeny" or "non-clone/progeny" .

While this may limit implementation costs in terms of traceability, segregation would still bring about considerable market disruption, since a large part of the market of food would be not accessible for certain FBOs. It is not possible to quantify these impacts.

However, considering that the number of animals concerned increases exponentially per generation (for example, for one single bull the number of offspring can be as high as 5,000 to 10,000; for the 2nd generation up to 140,500 descendants and up 662,000 of the following 3rd generation, etc. (see details in Annex XIII paragraph 2). The repercussions on the market place for food could be very substantial[74].

While quantitative figures are not available, any additional costs are particularly relevant for meat, which is already very price-sensitive and where margins are generally low.

The traceability of milk is even more difficult and costly than meat as it is systematically mixed from different animals at farm level and would need, separate collecting tanks[75] at farm level and all following stages of the supply chain (transport, dairy, retail, etc.). The dairy industry[76] explained that separate milk collection is strictly speaking feasible as it happens already for animals under medical treatment[77] but the likely consequence of

[74] Although it is unlikely that all reproductive material of a single cloned will be used in one country.

[75] Milk from the animals is mixed in one tank at farm level and dairy plant level ; separate systems already exist in some Member States for the collection of milk produced with specific requirements (related to animal feed, animal welfare etc.) but for larger production and with added value which compensate extra costs.

[76] The European Dairy Association (EDA).

[77] However, in this case, the traceability of the milk is no longer needed as it is destroyed and does therefore not enter the food chain.

having to label milk from progeny of clones is that farmers would avoid having those animals on their farms (see Annex III paragraph 3).

At the following stages of food processing (such as meat products, dairy products and milk ingredients such as casein, etc.) the link with the animals concerned becomes more difficult and costly to establish as it imposes detailed segmentation of the different food products (or raw materials) before the processing can take place[78].

As regards SME's, they cannot be excluded from any of the traceability requirements mentioned above. This option has therefore a potential to impact SME profit margins and growth in particular as they do not benefit from efficient production systems and/or economies of scale enjoyed by larger firms. Labelling could present particular challenges for micro and small enterprises but there may be some differences among Member States (see Annex X).

Thus, the traceability requirements for food poses risks of triggering significant impacts on the EU supply chain due to changes in third country trade patterns, mainly in meat (see Section 5.3.3. below). In case third countries' operators would be unable to label the food from offspring or from descendants, EU buyers would seek alternative supplies, which would result in changes in the distribution of demand across the supply chain.

The impacts on the different Member States would depend on several factors, in particular the importance of animal production and their dependence on imports. As 60 % of EU total production of dairy and beef originate in four Member States (France, Germany, Italy and United Kingdom), it could be assumed that in principle the farmers, breeders and FBOs in those Member States would be relatively more affected than those in the other Member States.

During the consultations, industry representatives expressed themselves against labelling of food from offspring and descendants (as highlighted in Annex II and Annex III paragraph 3). They also underlined the risk of trade disruption. In particular, representatives of European farmers /cooperative associations[79] consider that traceability extended to offspring represent a real administrative burden for the whole supply chain without benefit to consumers and would be faced with legal uncertainty as they would depend entirely on accuracy of information provided by third countries. They would rather be in favour of using voluntary information schemes. Professional organisations who responded to the "IPM consultation" also expressed themselves against (around 65%) labelling of food from offspring and descendants of clones (including the association representing the European food industry[80]).

Conversely consumer organisations, animal welfare associations and individuals, expressed themselves by a very high majority (between 75% and 90%) in favour of traceability system of reproductive material from clones and of labelling of food from offspring and descendants; results also showed that the absence of information was -wrongly[81]- perceived by consumers as an issue of food safety. Some industry

[78] This is confirmed by evidence from an on-going study 2013: 'Study on the application of rules on voluntary origin labelling of foods (VCOOL)' FCEC (forthcoming) commissioned by the Commission that shows that segregation of supply chains can have significant impacts, depending on the sector, company and production method. For the last factor, in the case of continuing production process, the change to batch production in order to ensure segregation of different supplies can imply significant investments and adaptations of production processes. This is particularly the case for processed products.

[79] European association of farmers /cooperatives (Copa Cogeca).

[80] Food Drink Europe.

[81] EFSA concluded there is no safety issue -see paragraph 2.1.

representatives[82] suggested during the consultations (Annex II) to inform generally consumers about the benefits and risks of cloning so that they would be well informed and would no longer have unfounded concerns.

c) Cost for changing the label of the food

Compared to the costs for ensuring traceability the costs for re-designing and re-printing labels are negligible. Estimates provided by the Commission impact report on food labelling range between 2000-4000 € for a small label change and between 7000-9000 € for full label redesign and per operator. Results of other studies also show limited costs (see Table 8 below).

Table 8 cost of labelling of food products

European Commission (2008) Impact Assessment Report on General Food Labelling Issues	Average cost at company level for a small label change: €2,000-4,000 per stock keeping unit (SKU); Additional cost for full label redesign: €7000-9000.
Private Label Buyer (2011) Special Report — Labelling	Cost of redesigning a small private label line of approximately 100 SKUs: $100-$3000 (€77 to €2320) in design fees ; Photography and illustration costs could more than double total cost
Defra (2010) Developing a Framework for Assessing the Costs of Labelling Changes in the UK	Average costs of changing a label for a food manufacturer: Voluntary redesign 4857 £/SKU (€6050) Implementing of new legislation 2945 £/SKU (€3670) ; Average costs for country of origin labelling for meat – large company: £600 - £1,150 (€748 to €1433).

Source: Defra (2010) Private Label Buyer (2011) European Commission (2008)

The economic impacts of labelling depend also on whether it is voluntary (sub-option4) or mandatory (sub-option5):

S*ub-option 4 (voluntary labelling)*: operators interested in differentiating their products would label food as not stemming from clones, offspring or descendants on a voluntary basis. They could in these cases offset the additional costs (linked for example to private control schemes) by a higher selling price in so far as there is market demand for such (more expensive) products and they can trace the food as described in section 5.3.2. (b) above.

S*ub-option 5 (mandatory labelling)*: unlike in the case of voluntary labelling, the costs set out above for sub-options 2 and 3, would fully incur if the labelling was mandatory. So if extended to offspring and descendants the additional cost would have to be borne by all (as explained in second indent of Section 5.3.5. below).

5.3.3. Economic impacts on trade with third countries

a) <u>sub-option 1: food from clones</u>

The cloning companies and breeders in some third countries already register their animals as clones on a voluntary basis as reported in the consultations (see section 1.2.2.). The cost for third country breeders has not been estimated but the cost for

[82] In particular European association of retailers (Eurocommerce) and European Livestock and Meat Trade Union (UEBCV).

identifying clones and their reproductive material can be reasonably the same[83]as estimated for the EU and therefore relatively low (e.g. around 20,000 € if companies decided to set up a database of clones and around 4,000 € per company to upgrade their registration and traceability system of reproductive material[84]).

b) sub-option 2: food from offspring

If food from offspring of clones would need to be traced and labelled to be exported to the EU, the adaptation costs would be much higher in third countries[85] than in the EU for food from offspring and descendants. Third countries generally[86] do not dispose of individual animal identification and of national databases as the EU does. It is very unlikely that third country operators would afford such costs for the EU market only. No third country has expressed any readiness to put in place the identification and traceability system.

In fact, EU's trading partners have repeatedly stated[87] that no measures should be imposed on the reproductive material and on offspring of clones by the EU; they underlined in particular that "*there is no scientifically justifiable basis for imposing a regulatory differentiation between the progeny of clones and other animals of the same species" and "that restrictions specifically aimed at food from progeny of clones – such bans or labelling requirements – could have negative impacts on international trade*". They also pointed out that "*science-based verification of audit and enforcement measures on progeny would be impossible*" and "*that systems put in place would be potentially subject to fraud*" (see Section 5.5. below on control).

This option may therefore create major trade disruptions with the EU[88]. Exports of live animals and their reproductive material to the EU would also need to specify whether they originate from offspring or descendants so that EU FBOs could label their future food accordingly.

The trade at risk for food could be substantial. Food imports of meat, milk and milk products are worth approximately € 3.6 billion each year[89].

c) sub-option 3: food from descendants

If food from descendants of clones would need to be traced and labelled to be exported to the EU, third countries would first need to put in place a system to trace the offspring and their reproductive material (as described in sub-option 2 above) which is unlikely. In addition, as for offspring adaptation costs would be much higher in third countries[90] than

[83] No ICF-GHK figure on cost calculation for third country companies.
[84] Result of ICF-GHK interview of private breeding companies.
[85] It has to apply both in the third country which export to the EU and also the other third countries from which either live animals or reproductive materials are supplied.
[86] The EU requirements for individual identification apply (as described in section 2.6.1.) only if these animals are exported live or their reproductive material is exported to the EU.
[87] *Joint statement on animal cloning for livestock production* of 16 March 2011 by Argentina, Brazil, New Zealand, Paraguay, United States at www.ustr.gov. Correspondence to Commission of 26. October 2012 signed by missions or embassies of Argentina, Brazil, New Zealand and United States in Brussels
[88] Meat and milk from our main trading partners may be exported to other international markets where consumption and financial resources are significantly increasing.
[89] Sources Eurostat 2012 – see table 2 in Section 2.6.3., paragraph c).
[90] It has to apply both in the third country which export to the EU and also the other third countries from which either live animals or reproductive materials are supplied.

in the EU. In view of the reluctance of third country operators to afford costs for tracing offspring and their reproductive material[91] this option would be clearly rejected by third countries. This sub-option may therefore create even more trade disruptions with the EU[92] in food and in live animals and their reproductive material.

5.3.4. Impacts on consumer protection

a) sub-option 1: food from clones

This option has a positive impact on consumers but as limited to food from clones, may not satisfy totally their request. In view of the consumers' negative perception towards cloning, it is likely that FBOs would not market this food if "mandatory labelling" is requested and would not label it either on a "voluntary" basis.

b) sub-option 2: food from offspring

This sub-option brings in principle an added value in terms of protection of consumer interests as it is to offer consumer choice but does not cover food from clones. There is also a considerable difference between voluntary and mandatory labelling for this type of food.

c) sub-option 3: food from descendants

This sub-option should offer an even higher benefit for consumers but would not make much sense if food from clones and from offspring would not be labelled. In effect, as shown in the consultations held, consumers have an interest for consumer choice linked to cloning and a partial one limited to descendants would not satisfy their expectations.

d) sub-option 4: voluntary labelling

In the case of *voluntary labelling* and if there is a market demand, the FBO could see an interest in differentiating their products. In this case, the voluntary labelling, would probably be "negative", i.e. specify that the food does not derive from cloning. FBOs have no interest in advertising food from clones, food from progeny of clones considering the strong negative attitude of consumers. It is therefore reasonable to assume that, based on consumer preferences, the market would decide for a "negative" labelling. This approach would however only offer a fragmented picture to consumers: not all FBOs would indicate the non-cloning origin of their food. As a result, consumers would not know whether unlabelled food is in effect derived or not from clones/progeny of clones. In addition, it is also possible that no FBO would decide to label, in which case consumers would not be informed.

[91] As it is a prerequisite to label food from descendants.

[92] Meat and milk from our main trading partners may be exported to other international markets where consumption and financial resources are significantly increasing.

e) sub-option 5: mandatory labelling

Conversely, *mandatory labelling* would create a clear picture for consumers and a level playing field for all operators. It should be "positive" (i.e. specify that the food derives from cloning) in order not to impose a burden on farmers, breeders and FBOs not involved in cloning. Mandatory labelling provides for a clear and uniform consumer information and thus put consumers in the position to choose but, as explained above, it is very costly to implement.

5.3.5. Impacts on food prices and employment

The extra cost of *positive voluntary labelling* (as described in Section 5.3.4. (d) above) would be borne by consumers and would probably relate to local food production (e.g. cheese produced exclusively from local bovine breeds) which uses exclusively traditional breeding techniques, therefore limiting the cost of voluntary labelling and giving to the food an added value.

In the case mandatory labelling (as described in 5.3.4. (e) above) there would be an impact on production costs due to the cost of the obligatory traceability system and the pressure on suppliers to be able to prove whether their products derive or not from offspring or descendants. There could be a price increase for food which could be transferred to consumers, if elasticity of demand is low. If not, this would have consequences on breeders, farmers and importers who would need to bear additional costs and even suffer a reduction in activity and employment, in particular for SME's.

5.3.6.. Impact on Animal Welfare

Under this option animal welfare problems are not addressed.

5.4. Option 4: temporary suspension of the technique and of imports of live clones, their reproductive material and their food.

5.4.1. Description of the option

The temporary suspension of the cloning technique in the EU would ensure that Member States do not adopt national measures for welfare reasons, offering thereby legal certainty and clarity. Live clones, their food and their reproductive material would therefore not be produced on the EU territory.

Imports of live clones[93], of their reproductive material would need to be suspended to ensure a level playing field between all breeders and farmers in the EU and ensure full consistency with the suspension of the technique in the EU.

As the technique may evolve over time and alleviate the welfare concerns, the suspension would need to be linked to a scientific review to assess whether it should be maintained or stopped, based on the possible technological evolution of the technique.

The suspension of food of clones would address consumer perceptions on the use of food from animal clones; it would complement the suspension of the technique and of marketing live clones.

[93] Including embryos, which are part of the cloning process as defined in Annex XIII paragraph 1, and which if the cloning process is successful, will become life clones.

5.4.2. Economic Impacts

As far as the EU is concerned, Member states have confirmed that cloning is not used for food production and therefore, no food from clones and no reproductive material from clones is produced on the EU territory. No food from clones has been imported so far in the EU and imports of live animals are in any case very limited. Therefore the expected economic impact of the temporary suspension of the cloning technique, of the clones and of their food is not expected to be significant to the contrary of reproductive material as explained below (Annex XI).

- Suspension of the technique

The suspension would have limited effect as no cloning is taking place in the EU. In the hypothesis that cloning for food production were more used in the EU, an increase in farming sector productivity could in principle be expected as the technique aims at reproducing elite animals[94]. However a recent economic study[95] estimated that the increase of productivity in the milk sector would be limited to 0.35%, which is minimal compared to the annual productivity increase of 1.5% observed in Europe between 2006 and 2009 without cloning activity.

Representatives of European farmers and agri-cooperatives[96] confirm that there is limited interest of European livestock keepers in cloning in view of the high cost of the technology but still consider that cloning could represent an interest in specific cases such as the preservation of valuable genetics (see summary of positions in Annex III paragraph 3 and Annex XIII paragraph 2 for the cost of cloned animals). This is also confirmed by the meat association[97] as other breeding methods work better and faster for the purpose of animal selection; nonetheless cloning might in their view become more relevant in the future (minutes of meeting in Annex II).

- Suspension of reproductive material of clones

The actual impacts on Member States of suspending the reproductive material of clones may differ according to the importance of their livestock. As shown in Table 1 (see Section 2.6.3. above), imports of reproductive material from third countries are on average low (2.5 %) but represent in certain Member States more than 20 %. It is not known how much of this imported reproductive material is obtained from clones or from conventional animals. It is difficult to assess whether there are major differences regarding the impact of this suspension according to Member States, particularly as the breeding sector requires continuous exchange of high quality reproductive material especially for high output species.

During the consultations and interviews with the consultants, EU breeders and farmers underlined that it is important to continue to have access to this genetic material to be

[94] In fact according to a relatively recent study, there should be an increase in the milk production if cloning were more used in Europe: Butler, L.J., McGarry Wolf, M. (2010) 'Economic Analysis of the Impact of Cloning on improving Dairy Herd Composition', AgBioForum, 13(2): pp. 194-207.
[95] Buttler study 2010 Economic analysis of the impact on improving dairy herd composition. AS bioforum 13(2):194-207.
[96] European association of farmers /agri cooperatives (Copa Cogeca).
[97] European Livestock and Meat Trade Union (UEBCV)

able to decide on their strategies to improve the productivity on a large base of genetics and improve or maintain their competitiveness (Annex XIII paragraph 4).

- Suspension of food from clones

As clones are not reared for food, it is unlikely that third country trading partners would from now on export food from clones to the EU in the future. This has not happened so far also because of the obligation to submit such food to a pre-market approval under the current Novel Food Regulation. Food industry in third countries where cloning technique is used would either remove food of clones from their food chain or remove it from the food exported to the EU. Taking into account the low number of clones and the fact that already today food cannot be imported as long as there is no PMA, this option has a very limited impact.

Regarding impact on competitiveness (Annex IX), the suspension of cloning technique in the EU is not expected to have direct effects on EU breeding companies, as there is no commercial cloning activity[98] expected for food production until 2020. Possible impacts on cost competitiveness are expected to arise through the additional costs incurred in assuring that inputs meet the terms of the suspension in the EU and the contingent risk of loss of access to imports of live animals, their food and reproductive material. EU farmers (especially in the bovine meat/dairy and ovine sectors) would benefit from loss of competition from imports of food (meat and milk production) in scenarios where exports from third countries to the EU are disrupted or lost.

Although *research* is not covered by this policy initiative, the potential for research may be affected if the commercial exploitation on the market is restricted. For example, cloning is used as a means to research in genome editing (which enables to identify at an early stage the productivity potential or other qualities of the adult conventional animals). Innovation in the breeding and farming sector could be more difficult to achieve in the EU and have serious long-term consequences on the ability of European farmers to access improved genetics, if European breeding organisations, which are global leaders, would relocate their activities outside the EU. It is therefore essential under this option, to consider the suspension as only a temporary measure so as not to discourage research and innovation in Europe and adapt the suspension to the evolution of the technique regarding its impacts on animal welfare.

As reported in Annex III paragraph 3, the organisations representing farmers, breeding sector, food industry as well as research institutes[99] expressed support for continuing and encouraging research in animal cloning. One organisation in particular[100] acknowledged the concerns of health and welfare linked to cloning, considered that they should be further addressed through research and that a broader analysis would be needed in the longer term to assess the benefits of cloning.

Regarding SME's, it is not possible to exclude them from the temporary suspension as this would undermine the objectives of providing for uniform conditions of production for the whole farming sector while ensure adequate protection of the welfare and health

[98] Source ICF-GHK study.
[99] European farmers/agri cooperatives (Copa Cogeca); European association of retailers (Eurocommerce); the European Association for Animal Production (EAAP); the International Committee for Animal recording (ICAR); the International Embryo Transfer Society (IETS); the French institute for agronomic research (INRA)
[100] European farmers/agri cooperatives (Copa Cogeca)

of animals. The impact on SME's mirror those expected on businesses as a whole (see Annex X).

Third countries would, under this option, not be allowed to export live clones, their food and their reproductive material to the EU. The impact for live animals would be limited as trade of live animals is generally very low (in total only around 40 bovines and around 800 porcine imported in the EU in 2011) the cost of identification and traceability of clones in third countries is relatively low (see paragraph a) Section 5.3.3 above). The impact on food would be insignificant in third countries as of today food from clones can only enter the EU market subject a pre-market authorisation, which has never been requested and as clones are not produced to this end it is unlikely the situation will evolve. The pragmatic approach already adopted by some third countries (see footnote 6 in Section 1.2. above) is to exclude the clones from the food chain on their territory. The suspension of exports of reproductive material of clones could have an impact but it is difficult to specify in the absence of any quantification of this material.

5.4.3. Impacts on consumer protection

This option has a positive impact on consumers: their concerns about animal welfare will be addressed as no cloning would take place in the EU. Consumers will have more confidence on the origin of products they are purchasing as food from clones would be forbidden and no food from offspring produced in the EU. However, they would not be able to make informed choices on food from descendants and imported food from offspring.

5.4.4. Impacts on prices and employment

The expected 'direct' employment impacts of the option of suspending the cloning technique and the use of clones is considered not significant because few EU jobs are sustained by commercial cloning for the farming sector. The potential employment impacts could arise through the induced and indirect effects of the legislation. Efforts to confirm compliance with the suspension legislation in particular for the reproductive material would create employment in the supply of verification services but this growth would come at the expense of employment elsewhere (more supply chain resources would be channelled into compliance activities at the expense of core business). It is however not possible to quantify such impact due to the lack of data available.

As regards food prices, no impact is expected as the technique is not currently used in the EU (see Annex IX).

5.4.5. Impact on Animal welfare

This option has a positive impact on animal welfare, as it creates a level playing field for all farmers and breeders in the EU who no longer be able to make recourse to it. The suspension would be maintained a long as the concerns on animal welfare and health are not alleviated and be subject to scientific review so as to assess whether it should be maintained or stopped.

5.5. Impacts on control (applicable to all options including non-policy change)

Control on the implementation of any measure on cloning by control authorities can only be based on documentary and traceability systems, set up and managed by the successive operators along the food chain including in third countries where the cloning activity takes place.

Physical controls based on analytical methods are not possible as the DNA of the clone is identical to the DNA of the donor and therefore the derived products (reproductive material and food) of clones and of progeny cannot be distinguished via laboratory testing. This could create potential legal uncertainty for operators, who would not be in a position to attest by analytical methods that the animals, reproductive material or food they have procured is derived or not from cloning.

There would be no additional costs for Member States' control authorities as regards the controls of intra-Union trade and imports of live animals, their reproductive material and their food. The absence of additional costs is due to the fact that live animals, their reproductive and food are already submitted to specific official controls both as regards those produced in the EU and those imported[101]. Therefore, the additional information required as a result of this policy initiative would not trigger new activities by Member States. Conversely, additional resources would be required from FBOs (as described in Section 5.3.2) to check the reliability of the traceability systems, which support the labelling of food of clones and their progeny.

The effectiveness of control relies primarily on third countries' readiness to put in place the identification and traceability systems of the clones as any of the policy options are dependent on this prerequisite. Controls in third countries can be ensured by the Food and Veterinary Office (FVO) which would verify that breeding companies and food operators exporting to the EU have put in place the necessary identification and traceability systems of the animals, reproductive material and food to ensure proper and reliable information. There would be no impact on the EU budget as the FVO already carries out inspections in the fields covered by this policy initiative.

6. COMPARING THE OPTIONS

The ranking of the impacts and objectives per option is given in detail in Annex XII.

A summary of the ranking is given at the end of this Chapter. The impacts in terms of economic (costs), consumers (freedom of choice) and social (prices of food & employment) are compared for the various options. As the options have no or very limited impact on environment (biodiversity), this criterion does not appear relevant to rank the options. All measures on cloning would produce costs for operators for part or

[101] Intra-Union trade and imports of live animals and reproductive material must be accompanied by "health certificate" delivered by official authorities in Member States and Third Countries as described in Annex III.

for the food chain. These costs need to be justified balanced by added value in terms of animal welfare and consumer protection.

6.1. Comparing the options in terms of impacts

6.1.1. Option 1 (no policy change)

This option has the lowest economic impact but only partially addresses consumer protection and welfare. It implies costs on FBOs interested to market food from clones as this requires pre-market approval of food. It allows labelling of approved products. Yet as there is no commercial interest in the marketing of food from clones, the actual implementation of PMA is unlikely.

As to welfare, in light of the EFSA opinion, full implementation by Member States of the Directive 98/58/EC on animal welfare implies in principle that the cloning technique is not used for food production in the EU. This option has thus a positive impact on welfare. It has no impact on FBOs in general as they can under this option continue to import animals and food.

6.1.2. Option 2: Pre-market approval of food from clones to food from offspring and descendants

This option triggers impacts due to the multiplication of application dossiers for the required market authorisations for both EU and third country operators, to unavoidable additional burden on EFSA, to the necessity to trace the animals and their reproductive material in addition to the food. In the absence of food safety issues, the measures under this option are not proportionate in particular as regards food from offspring and descendants.

6.1.3. Option 3: labelling of food (from clones, offspring and descendants)

This option requires the traceability of animals, of their reproductive material and of the food to enable FBOs to label the food.

a) For sub-option 1 (labelling food from clones), the impact on both FBOs and third countries is limited.

b) For sub-options 2 and 3 (labelling of food from offspring and descendants) the costs for traceability would be substantial. The costs increase even further with the inclusion of each generation and with non-segregated food supply chains because of the underlying need for more sophisticated traceability systems. This is particularly the case when the labelling *is compulsory* (sub-option 2 and 3 combined with sub-option 4).

c) in the case of *voluntary labelling* of food from offspring or from descendants (sub-options 2 and 3 combined with sub-option 4): FBOs would be able decide to label the "non-cloning origin" of their food if they dispose of the necessary information upstream. If this information is limited to the traceability of clones and their reproductive material and offspring, as foreseen in the Commission report, the impact is limited. However as labelling would be decided by FBOs, consumers would only be informed scarcely.

6.1.4. Option 4: temporary suspension of the technique and the use of clones (food and reproductive material)

This option ranks higher than option 1 as it creates legal certainty for all EU operators and applies in a coherent manner to the use of the technique as wells as to the use of clones. Its efficiency depends on its scope:

(i) if limited to the technique, to clones and their food, the impact on EU FBOs and trade is limited as trade, if any, is likely to be extremely low and FBOs overall have no interest to market food from clones. The suspension of the technique would not impact negatively on innovation and research as it would be temporary and signal that research, (not touched upon by this policy) needs to be pursued. The possible use of imported reproductive material of clones (as mentioned in section 5.4.2. second indent above), justified for economic reasons, would not diminish the effects of this measure as the welfare of animals reared in the EU would be secured by the suspension of the technique in the EU and the suspension of live clones.

(ii) if the suspension would also include that of reproductive material of clones, it offers the highest coherence with the objective of animal welfare but may prevent EU breeders and farmers to have access to this genetic material, which they may have had so far, and thereby undermine their competitiveness.

Therefore the elements of this option, which rank highest in terms of animal welfare, are the suspension of all elements except the reproductive material from clones. Otherwise, it ranks lower than option 1.

6.2. Comparing the options in terms of objectives for coherence and efficiency

6.2.1. Option 1 (no policy change)

This option is coherent with the objective of consumer protection but only as regards food from clones. For food from offspring and descendants, this objective would not be fulfilled. In addition, this option adds costs linked to pre-market authorisation and risk assessment.

The implementation of Directive 98/58/EC is coherent with the objective on welfare. It is not efficient as it applies only to the cloning technique and not to the use of clones, which means that farmers and breeders can still import them and use them.

6.2.2. Option 2: Pre-market approval of food from clones to food from offspring and descendants.

This option provides for consumer protection[102] as it reassures consumers on safety as it applies to all food of the animals concerned. In the absence of "novelty" for food from offspring and descendants and in the absence of food safety issues, it is unjustified and incoherent to impose any PMA for this type of food, particularly as the food in question must in any case comply with the legislation on food safety (hygiene, control, additives, etc.). The PMA for offspring and descendants is also disproportionate; as described in section 5.2.2 above, unjustified costs would need to be borne for FBOs (linked to risks

[102] Charter of Fundamental Rights of the European Union (2000/C 364/1) Article 38 on Consumer protection.

assessments and application dossiers, to the required traceability requirements of the animals concerned and of their food) and trade disruptions most likely.

Therefore, the element of this option, which ranks highest, is the pre-market approval of food from clones.

6.2.3 Option 3: labelling of food (from clones, offspring and descendants)

Sub-option 1 (labelling of food from clones) would rank highest as not having any impact on trade but this type of food is unlikely to be marketed.

Sub-option 2 (labelling of food from offspring) combined with sub-option 5 (mandatory labelling) for all food, would not be efficient as very difficult to put in place. In addition, it would considerably disturb trade with third countries and not attain the general objective (as described in section 3.1).

If sub option 2 is combined with option 4 (voluntary labelling) it would rank lower than mandatory labelling and option 1.

Sub-option 3 (food from descendants) would be totally inefficient if mandatory (combined with sub-option 5) as unfeasible to put in place. If voluntary (combined with sub-option 4) it would not meet consumer expectations. Sub–option 3 ranks therefore lowest.

Therefore, the elements of this option, which would rank highest in relative terms are the mandatory labelling of food from clones (sub-option 1 combined with sub-option 5) and of fresh meat of offspring (elements of sub-option 2 combined with sub-option 5).

6.2.4. Option 4: temporary suspension of the technique and the use of clones (food and reproductive material)

This is the only option (together with option 1) which addresses animal welfare. In terms of achieving the objective of creating uniform conditions for farmers while resolving the welfare issue, this option ranks higher than option 1. The freedom to conduct business might be restricted but this would be justified for the purpose of protecting animal health and welfare[103]. The objective of animal welfare can therefore be best achieved at Union level with this option. The suspension of the use of reproductive material of clones would not be coherent with the objective of safeguarding the competitiveness of the EU farming sector. Therefore, the elements of this option, which rank highest, are the suspension of the technique, of imports of clones and of food.

[103] Charter of Fundamental Rights of the European Union (2000/C 364/1): Article 16 on freedom to conduct a business.

6.3. Table summarising the impacts

Table 9 Summary of comparison of options of Section 6

OPTIONS			Economic impact/ costs	Effectiveness in reaching the objectives	
				Animal welfare	Consumer protection
Option 1 No Policy Change: Pre-market approval + labelling of food from clones on case by case + Directive 98/58/EC on animal welfare.			**0**	**+**	**+**
Option 2 Pre-market approval : Food from clones			**0**	**0**	**0/+**
		Food from offspring and descendants	**- - -**	**0**	**0/+**
Option 3 Labelling of food[104]	**Food from clones**	Mandatory labelling of food from clones (sub-option 1 + sub-option 5)	**0**	**0**	**++**
	Food from offspring	Voluntary labelling of food from offspring (sub-option 2 + sub-option 4)	**0**	**0**	**0/+**
		Mandatory labelling of food from offspring (sub-option 2 + sub-option 5)	**- - -**	**0**	**+++**
	Food from descendants	Voluntary labelling of food from descendants (sub-option 3+sub-option 4)	**0**	**0**	**0/+**
		Mandatory labelling of food from descendants (sub-option 3+sub-option 5)	**- - -**	**0**	**+++**
Option 4 (Suspension in EU)	Cloning technique		**0**	**+++**	**++**
	Clones		**0**	**+++**	**++**
	Reproductive materials of clones		**- -**	**0**	**0**
	Food from clones		**0**	**0**	**++**

[104] Option 3 is divided in five sub-options: sub-option 1 (food from clones), sub-option 2 (food from offspring), sub-option 3 (food from descendants), sub-option 4 (voluntary labelling), sub-option 5 (mandatory labelling).

+++ strongly positive; ++average positive +limited positive, - - -strongly negative, - - average negative; - limited negative; 0 no effect.

7. MONITORING AND EVALUATION

In order to monitor and evaluate how the two specific objectives are implemented and performed in the various options, the following monitoring indicators could be used:

Objective 1: *To ensure uniform conditions of production of farmers in the EU while protecting health and welfare of farmed animals*: Scientific progress could be monitored by EFSA for both option 1 (to assess whether cloning is still a breeding that causes unnecessary pain) and option 4 (to measure whether the suspension should be stopped, amended, for example in terms of coverage or be maintained);

Objective 2: To protect consumer interests as regards food from cloned animals :

- for both options 1 and 2, the number of applications made (and approvals given with labelling requirement) for food subject to a pre-market authorisation enables to assess which food has been authorised and which food (if any) could not be authorised and for which reasons;

- regarding option 3, specific surveys at national or EU level could assess which food is labelled on the EU market, if consumers' attitude has changed towards cloning, the effects of the measures on FBOs; statistics[105] on the number of clones/offspring/descendants raised in the EU or imported would also give a picture of their share in the EU livestock.

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[105] Eurostat, TRACES (Commission management tool for tracking the movement of animals and of products of animal origin from both outside of the EU and within EU territory).

ANNEXES

ANNEX I: GLOSSARY

"Artificial Insemination": Can be described as the injection of semen from a superior-quality male in the reproductive tract of a female to make her pregnant.

"Breeding": Consists in selecting the most suitable animals as parents of the next generation so as to improve[1] on a regular basis the performance (in milk production, amount of muscles, resistance, longevity etc.) of the following generation(s). The improvements can bring high economic returns at breeding and farm level and be disseminated widely especially thanks to the high reproductive rates of the animals, the use of artificial insemination, embryo transfer, in-vitro fertilisation and more recently the use of genomic selection.

"Breeding animals": Pure breed animals companies with high genetic value which produce reproductive materials (semen, embryos and ova) to perform artificial insemination or embryo transfer (males and females detained by farmers which are used for natural mating or calf production are excluded).

"Cloning": Means a technique of asexual, artificial reproduction with the aim of producing an identical or nearly identical copy of the original animal by transferring the nucleus of a cell from the donor animal into an enucleated oocyte which is subsequently implanted into a surrogate mother (cloning does not involve any genetic modification).

"Conventional animals": For the purpose of this report, conventional animals means all animals other than those having a cloning background (clones, offspring and their descendants).

"Descendants (second and further generations)": Means an animal produced by a traditional breeding technique, where none of its parents is a clone but at least one of its ancestors was a clone.

"Embryo Transfer": It consists in using a very good female to produce embryos (with the genetic material of both the female and the male). Each embryo from this female is transferred to surrogate mothers to give birth to the actual animals.

"EU Food Law": (Regulation (EC) 178/2002): establishes the common basis for food law in Member States and includes common definitions, general provisions and specific requirements such as food traceability.

"Generic authorisation": The pre-market authorisation is granted to all operators who can put the authorized product on the EU market provided they respect all the specifications and conditions of use.

"Genome editing": Small changes or moving polymorphisms within a breed.

"Genomic Selection": Is a technology that incorporates information from tens of thousands ADN positions to determine directly from the genome of an animal its genetic merit and future production and performances.

[1] This is done by using the naturally occurring genetic variations that exists always between individual animals.

"Gross profit margin": describes the difference between revenue (price of a product) and cost (total costs incurred in production).

"Herd book": A book containing the list and pedigrees of one or more herds of choice breeds of cattle, pigs etc.; - also called herd record, or herd register.

"Individual authorisation": The pre-market authorisation is only granted to the operator who filed the application.

"In-vitro fertilisation": Is a process by which an oocyte is fertilised by semen outside the body of the animal to be then transferred into a surrogate female.

"Offspring (first generation)": Means an animal produced by a traditional breeding technique, where at least one of its parents is a clone.

"Pre-market approval": Is a regulatory measure according to which, new food products have to be authorized by the competent Authorities before being placed on the EU market.

"Reproductive material": Means the semen, ova and embryos of animals to be used for traditional breeding techniques. These materials are produced by the breeding companies and used by farmers to obtain animals intended for meat and milk production.

"Segregated food supply chain": Means that food operators would treat separately (on a separate processing chain or at a different period) the carcasses, the meat or the milk of clones and their progeny in order not to mix it with meat or milk from conventional animals. Basic identification and traceability (e.g. colour code) is sufficient not to mix the two types of food products.

"Selection farms": Farms of animals with high genetic values used for the genetic improvement of specific breeds. In order to estimate the genetic value of these animals it is necessary to have an individual identification of them and at least to know the father and the mother of the animal.

"Whole food supply chain": Means that food operators would treat simultaneously and on the same processing chain the carcasses and meat from i) clones and their progeny and ii) from conventional animals. This would require the setting up of new traceability systems or the upgrading of existing ones (such as those used for beef labelling of the origin). N.B. not possible for milk when mixed in the same tank.

"Surrogate mothers": A surrogate mother is a female animal who bears a cloned embryo. She carries and gives birth to an animal that she is not the biological mother.

"Traditional reproduction techniques": Are artificial insemination (AI), embryo transfer (ET) and natural mating (NM) used in the sexual reproduction of farm animals.

"Veterinary Health Certificate": Is an official document signed by the official veterinarian certifying in accordance to general provisions laid down in Directive 96/93/EEC that the animals or products thereof meet certain generic (e.g. no clinical sign of disease) and specific (e.g. being tested with negative results) health requirements.

ANNEX II: MINUTES OF THE ADVISORY GROUP AND BILATERAL MEETINGS WITH STAKEHOLDERS

1. Plenary meeting of the Advisory Group on the Food Chain and Animal and Plant Health 16 March 2012 (Point 5 of the agenda).

2. Working Group of 14 May 2012 on the Impact Assessment of measures on animal cloning for food production in the EU (Agenda and Summary).

3. Plenary meeting of the Advisory Group on the Food Chain and Animal and Plant Health 26 November 2012 (Point 8 of the agenda).

4. Report on the meeting of 20 September 2012 with EFFAB (European Forum of farm Animal Breeders).

5. Report on the meeting of 25 October 2012 with EDA (European Dairy Association).

6. Report on the meetings of 5 September and 10 October 2012 with UECBV (European Livestock and Meat Trading Union).

7. Report on the meetings of 12 September and 8 November 2012 with COPA-COGECA (European Farmers and European Agri-cooperatives).

8. Report on the meeting of 18 December with UECBV (European Livestock and Meat Trading Union).

1. Plenary meeting of the Advisory Group on the Food Chain and Animal and Plant Health 16 March 2012 (Point 5 of the agenda).

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

COM presented the state of play of the Commission impact assessment on animal cloning for Food production; briefly clarified the terminology used and explained individual roadmap policy options. COM offered links to all available relevant information and informed participating organisations of the various general, as well as targeted consultations which are scheduled in the near future. COM also mentioned its request to EFSA to update its opinion on cloning by June 2012.

COM presented the external study for the collection and analysis of data, the main objectives of which are to analyse the feasibility of options and to assess socio-economic and environmental impacts. COM asked participating organisations to provide written positions by 30 April 2012 and that public consultation using the Interactive Policy Making tool (IPM) will be available on its website by April. The impact assessment will be finalized by the end of 2012. COM's proposal on animal cloning for food production is planned for 2013, as indicated in the road map which has been recently published.

COM's contractor, GHK Consulting, presented the main goals of its study, which are to examine the feasibility and the impacts of various policy measures that would govern animal cloning and the marketing of derived products in the EU, ranking from suspension of the cloning technique in the EU, the setting up of traceability systems for reproductive materials from clones and live clones and offspring, to pre-market approval, traceability and mandatory labelling for derived foodstuffs.

GHK explained that the analysis will apply to several species (cattle, pigs, sheep, goats and horses) and be built around a model of the market that captures the EU production, imports and exports and a simplified schematic representation of the full supply chain. The external study will be finalized in the summer of 2012.

Comments and questions raised:

FESASS commented on the differences in legislation in the EU and 3rd countries and asked how the different implementations of legislation would be treated in the study.

GHK confirmed that these would be considered in the study.

FOODDRINKEUROPE asked what types of questions are in a questionnaire sent to the Member States and whether they are related to traceability. It also raised the question of novel food and asked when it is foreseen to come forward with the legislation on cloning and novel food, whether they would be separated and what the time line is.

COM clarified that at the moment it has only been decided to present a proposal on animal cloning, which is scheduled for 2013. Regarding the novel food legislation, there is no decision yet on when it might be presented. With regard to the questionnaire sent to the Member States, COM pointed out that the questions are related to traceability and possible labelling and recording in the Member States.

EDA expressed concern about the feasibility of tackling such a broad issue within the given timeline. If stakeholders are to be asked to provide relevant data, sufficient time is needed.

In reply to a request from EUROGROUP FOR ANIMALS on public consultations, COM gave further details, in particular that the questionnaire for the general public will be available on the *Your Voice in Europe* website in April for a twelve-week period.

COM/GHK clarified to FESASS that there is indeed the intention to categorise different costs in the study so that it shows clearly which costs are related to the setting up of the traceability and labelling system.

2. Working Group on the Impact Assessment of measures on animal cloning for food production in the EU (Agenda and Summary).

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Safety of the Food Chain
Innovation and Sustainability

Brussels, 14 May 2012
D(2012)

Working Group of the Advisory Group of the Food Chain, Animal Health and Plant Health on the impact assessment of measures on animal cloning for food production in the EU

Summary report

14 MAY 2012

Participants:

Commission - DG Health and Consumer:

Chantal Bruetschy (Head of Unit E6)

José Luis de Felipe Gardón (Deputy Head of Unit E6)

Stakeholders: please see list attached

1. Introduction

Ms Bruetschy, Head of Unit E6, chaired the meeting. She explained that the purpose of the meeting, in the framework of the impact assessment procedure, was to collect the stakeholders' views on the possible measures to regulate the use of cloning for food production in Europe, as set out in the published roadmap. The aim of the impact assessment is to define the most appropriate policy while ensuring the functioning of the internal market, respecting the WTO agreements and guaranteeing consumer information.

2. General positions on cloning

CIWF stated its position against cloning, based on two general problems: the welfare issues for clones and the surrogate mothers and the fact that the technique will be used to produce copies of animals genetically selected for high yields despite the EFSA reports showing that high yielding animals often suffer from serious health and welfare problems. In this regard, the representative felt that current animal welfare legislation is not up to date on problems of high yield animals. He emphasized the need for ethic consistency and thus that any measure on offspring should take into account that such animals are the result of the use of the cloning technique at some stage. He also worried that feasibility hurdles would serve as an excuse for inaction. Finally, he stressed that the absence of safety issues does not make the problem of cloning less relevant to consumers.

UECBV is of the view that cloning is not of great interest for the meat industry in Europe today, as other breeding methods work better and faster for the purpose of animal selection, but that cloning might become relevant in the future. However, cloning is currently used in third countries that have trade relations with the EU. The uncertainty regarding the usage of the technique in the world would make identification and labelling requirements difficult to implement. The representative also felt that the tracing systems in place for cattle should not lead to an excessive and unfair burden on the beef industry.

CLITRAVI said that WTO obligations must be respected, as import restrictions for products related to cloning (reproductive material, live animals and food) could be negatively perceived as technical barrier to trade.

COPA-COGECA stressed the importance of SME's in Europe and that the majority of farmers are against cloning for food production purposes, since consumers are against it. However, Europe cannot isolate itself from the rest of the world, and the use of the cloning technique outside the EU has to be carefully assessed. The fact that food from clones and offspring is not distinguishable from other food raises feasibility issues for traceability and labelling.

EFFAB mentioned that measures must be enforceable and that animal cloning is a reproduction technique, not a breeding technique.

HOLSTEIN UK felt that progeny from clones and food from clones and offspring would be hard to trace and, therefore, expressed concern about the effectiveness of possible legislation.

EUROGROUP for ANIMALS is not in favour of cloning for the same reasons exposed by CIWF. They believed that farmers that buy breeding material to improve the yield of animals should have information on where the reproductive material comes from.

BEUC stated its position against the use of cloning for food production, given the great dissent of consumers. The representative stressed that consumers should have the right to choose and that, if marketed, food from clones and offspring should be labelled.

FOODDRINK EUROPE has yet no official position on cloning; however it felt that, given there is no food safety but only an animal welfare issue, the topic relates more to actors upstream in the agricultural industry than to consumers. Possible measures should avoid trade disruptions, be proportionate and enforceable, and preserve the trust of consumers in the food industry.

3. Detailed discussion

To help the discussion, it was suggested to divide the theme into four main streams:

a) current traceability of reproductive material/live offspring, b) possible tracing of reproductive material from clones/live offspring from clones, c) labelling and d) pre-market approval

a) Current traceability of reproductive material/offspring

Cattle: HOLSTEIN UK said that for pedigree animals, it is possible to know the ancestry of animals and reproductive material.

COPA-COGECA and UECBV observed that not all animals are purebred and registered in herd books, as it is not mandatory. Moreover, COPA-COGECA and HOLSTEIN UK pointed to the cross-bred animals, which are also not in the herdbooks. The percentage of cross breeds varies between 25% and 50 %, depending on the breed.

FVE held that farmers sometimes trust an expert breeder and choose the semen based on production expectations rather than based on its ancestors. In relation to this, COPA-COGECA mentioned that farmers may follow breeding programs to select the reproductive material they buy. In both cases, farmers may not be interested in the identity of the sire.

Pigs: In most cases, breeding takes place with artificial insemination (AI) and no longer with natural mating (in some countries AI is reaching 80-90 %). COPA-COGECA said that, when AI is used, it is done with fresh and not frozen semen. Semen is traded in limited amounts.

Goats: Farms are usually small and not attached to breeding organizations. The percentage of AI is very low (it dropped considerably compared to 20 years ago, maybe between 5 % and 10 %, exact figures are not available),UECBV observed that in the Netherlands production of breeding material for goats was stopped because it was not profitable.

b) Possible tracing of reproductive material from clones/live offspring from clones

HOLSTEIN UK said information on whether an animal is a clone can be included in the supporting documentation of pedigree animals, but that it would be difficult to verify the reliability of this information. However, not all Holsteins have a pedigree. The representative stressed that individual identification of animals does not exist in many countries, making a global certification system an unlikely possibility.

UECBV said that, in order to be credible, a declaration on import certificates should not be based on the information on herd books only. It should instead be supported by official certification from public authorities. However, the representative considered that this measure could put the EU at risk of retaliation.

A database with information on individual animals, similar to the one in place for European cattle, would only be useful if the major trade partners had one. This is not seen as a realistic possibility. Finally, a system restricted to European production would represent an unfair burden on European farmers, decreasing their competitiveness.

CLITRAVI stated that a traceability system based on unreliable information would open the possibility for food scares. The representative doubted that third countries, such as the USA, would accept a measure requiring official certification of imports.

EDA noted that, today, imports are allowed on the basis of the information provided by official certificates. They thus considered that inspections on procedures and official certificates would be sufficient to guarantee that foreign producers provide reliable information on reproductive material from clones and live offspring. Although less preferred, a system of "own check" procedures could work as well. This would force foreign producers, who wish to export into the EU, to have a procedure in place to guarantee reliable information.

EFFAB reiterated the statement of COPA-COGECA on the impossibility of checking if a product involved cloning at some stage. FVE mentioned that a clone can be recognized by testing DNA.

Reacting to CLITRAVI's statement on unreliable traceability system and food scares, BEUC stressed that information is key to building consumer confidence in the food system. Rather than waiting for news stories on "cloned" food to appear in the media – which will also result in costly food scares -, BEUC emphasized the importance to have, as soon as possible, a reliable system in place to inform consumers. UECVB thought that giving reliable information to consumers is important in this respect and mentioned the hormone free beef scheme as an example.

Horses are usually not bred for food production purposes, but EDA said imported sports horses can be slaughtered and enter the food chain. COPA-COGECA said AI is not allowed in several major breeding organizations. Only geldings could need to be cloned, as they cannot reproduce naturally.

c) Labelling

CIBC noted that mandatory labelling would have the consequence that food from clones and offspring from clones would not be marketed and that no label would then exist in Europe.

UECVB are not in favour of labelling. They stressed that labelling must be based on a good traceability system with strong guarantees on the reliability of the initial information. This is particularly important because the technique is perceived negatively by consumers. FVE suggested cloning could become a positive attribute in the future and that labels would be perceived as a value added to products. UECVB responded that, currently, this is not the case. They felt that the likely consequence of labelling would be the interruption of imports of reproductive material from clones.

EUCOLAIT noted that any measure relating to food from offspring and descendants of clones (suspension, pre-market approval or mandatory labelling system) would effectively block imports of dairy products and likely be challenged at the WTO. As regards labelling of products from offspring and descendants born in the EU, EUCOLAIT considered that it would be difficult to label processed milk products because the milk comes from many animals. EDA responded that, in the production process, separating the milk of specific cows is feasible and is done regularly in the case of animals under medical treatment. This could be done also for cows that are clones or offspring from clones. However, it is likely that as a consequence farmers will avoid having clones and offspring from clones in their herd. Finally, EDA stressed that a labelling system should not be retroactive and should include a transition period.

CLITRAVI expressed the view that labelling of food from clones could create trade disruptions.

CIWF noted that retailers and consumers in Europe do not want cloning and that justifying measures with the WTO would not be impossible. The argument would need to be constructed properly, based on consumer perceptions and behaviour, the clause on public morals and case law.

FOODDRINK EUROPE does not have an official position on labelling yet. It noted that in Europe, so far, labelling has killed technology and that it would be difficult to guarantee reliable information at all. It believed that labelling of food from clones could create trade disruptions.

BEUC stressed the importance of informing consumers and that trust is always involved in the business to business relation between producers and their suppliers. Consumers have not supported products deriving from new technologies when they do not see the benefits for them of using such technologies. Also in the US, consumers have strong concerns over the use of animal cloning for food production and consumer organizations in the EU and US, through the Transatlantic Consumer Dialogue (TACD), issued a joint resolution in 2008 for the suspension of food from clones. Reacting to a comment that it would be very difficult to impose labelling on imported food of animal origin, the representative said that, even though direct labels would be the preferred option also for third country products, country of origin information could be used by consumers as an indication of the possibility that cloning took place at some level of the production chain.

EUROCOMMERCE has no position on labels yet. In general, retailers aim at offering consumers what they expect.

COPA-COGECA expressed a preliminary position against labelling of food from offspring of clones because it does not see traceability as a feasible possibility. Farmers are not likely to take the risk of having clones and offspring form clones in their herds. The result of labelling would be to segregate the production flows of food from clones and their offspring and food from conventional animals. In the medium term, restricting the commercial use of the cloning technique could have a negative impact on the competitiveness of European farmers. They considered that if a certification system would be required only at European level, an unfair burden would be put on European producers with respect to producers outside Europe. Finally, COPA-COGECA underlined that research would only be pursued if it has prospects of commercial application.

EFFAB worried that labelling and traceability measures would hinder research on cloning in Europe, which would risk decreasing the competitiveness in the future.

There were no particular comments on descendants of offspring of clones or on the pre-market approval measure.

AVEC, ECSLA, FESASS, INFOAM EU, UEAPME and OIE did not express an opinion on the questions raised.

4. Conclusions

COM thanked the stakeholders for their contribution and asked them to complete the public consultation questionnaire with all the necessary technical explanation and data where possible.

Participation list

Table 1: ADVISORY GROUP MEMBERS

1	AVEC	Association of Poultry Processors and Poultry Import and Export Trade in the European Countries
2	BEUC	Bureau Europeen des Unions de Consommateurs
3	CLITRAVI	Centre de liaison des Industries Transformatrices de viandes de l'Union Europeenne
4	COPA-COGECA	Comité des organisations professionnelles agricoles de l'Union européenne – Confédération générale des coopératives agricoles de l'Union européenne
5	ECSLA	European Cold Storage and Logistics Association
6	EDA	European Dairy Association
7	EUROCOMMERCE	European Representation of Retail, Wholesale and International Trade
8	EUROCOOP	European Community of Consumer Cooperatives
9	EUROGROUP FOR ANIMALS	Eurogroup for Animal Welfare
10	FESASS	Fédération européenne pour la santé animale et la sécurité sanitaire
11	FoEE	Friends of the Earth Europe
12	FOODDRINK EUROPE (former CIAA)	Confederation des Industries Agroalimentaires
13	FVE	Federation of Veterinarians of Europe
14	IFOAM-EU GROUP	International Federation of Organic Agriculture Movements — European Union Regional Group
15	UEAPME	Union européenne de l'artisanat et des petites et moyennes entreprises
16	UECBV	Union européenne du commerce du bétail et de la viande

Table 2: NON MEMBERS

1	CIBC	Confederation International de la Boucherie et de la Charcuterie
2	CIWF	Compassion in World Farming
3	EUCOLAIT	European Association of Diary Trade
4	EFFAB	European Forum of Animal Breeders
5	HOLSTEIN UK	Breed Society
6	OIE	Office International des Epizooties

3. Plenary meeting of the Advisory Group on the Food Chain and Animal and Plant Health 26 November 2012 (Point 8 of the agenda).

Impact assessment for possible measures on animal cloning for food production – state of play on information received from stakeholders

The Commission thanked the members for the various position papers received on cloning issue and the responses to the IPM consultation which are being examined. Commission also thanked for the technical explanation (breeding issues, herdbooks, genomics, etc.) given in bilateral meetings with COPA-COGECA, EFFAB, EDA and UECBV.

The Commission acknowledged the difficulty for the members to obtain data related to the use and imports of reproductive materials in the EU and invited them to share information on this for all relevant species (bovine, but also porcine, caprine and ovine) in so far it is not commercially sensitive. Several members agreed to do their best and mentioned the fruitful cooperation with the Commission services on the technical understanding of the all related aspects.

The Commission indicated that the work on the impact assessment report was on going and the legislative proposal on animal cloning for food production is planned for adoption by mid-2013.

4. Report on the meeting of 20 September 2012 with EFFAB (European Forum of farm Animal Breeders)

BTO report of E6 meeting with EFFAB on cloning issue (20/09/2012)

Present:

EFFAB, Topigs, UNCEIA representatives.

SANCO: C. Bruetschy, J.L. De Felipe, J.F. Roche

EFFAB is the European organisation representing the breeding sector for farm animals.

1. Use of A.I. and embryo transfer

- **Bovines**
  - EU average of 75% of A.I. for milk production and < 10% for meat production (except for BE breed "blanc bleu belge" with very high %).
  - EU imports of reproductive materials mainly for milk production. Around 10 % of semen is imported (milk) mainly to UK, Irl, NL, Italy and to lesser extent DE, BE, FR etc.
  - Costs for semen doses: 10-20 € for standard bull, 2-300 € for top bulls.
- **Porcines**
  - Use of locally produced fresh semen for production farms
  - Use of frozen semen (both from EU and third countries) limited to nucleus herds (selection: multiplication farms). Only 300 bores (males) at world level are used for A.I. with frozen semen.
  - Huge development of A.I. for meat production (95%).
  - Mixing of semen to increase fertility.
  - Cloning not interesting due to short intervals between the generations and quick genetic improvements;
- **Ovines**
  - Very limited use of A.I. for ovines because not economically worthwhile (for Lacaune breed for Roquefort production and only for selection farms for meat production).
  - Use of fresh semen only: No imports of semen.
  - Mixing of semen to increase fertility.
- **Caprines**
  - Use of A.I. for selection/ multiplication farms only.
  - No imports of semen.
  - Mixing of semen to increase fertility.

2. Traceability for reproductive materials

- Imports of semen only for pure breeds with full identification of the donor (EU health certificates).
- No mixing of semen collected by semen centres (except for porcine and ovine);
- Straws: identification of collect centre, animal individual identification, and date of collection.
- DNA profiles to check the identity of the donor and its parentage but not applicable to make distinction between the original bull and its clones.

- Use of cloned bovine for reproductive materials to continue the semen production of top bulls when the original animals are no longer in use but overlap cannot be excluded as frozen semen may be stored up to 50 years.

- No problem to trace in the EU imported semen from clones once it has been declared as such (no obligation under EU legislation to do so), but no idea about feasibility of such traceability in US / Canada.

- EFFAB has set up a code of Good Breeding practices for bovines, porcine and poultry which is applied by breeding companies which are members of EFFAB but not by individual farmers which can directly import reproductive materials: to impose transit through EU agreed semen centres for registration and control.

- Difficulty to control possible EU measures requesting third country exporters to identify and trace semen from clones: it cannot be based on DNA testing but on traceability systems based on documents. To set mutual agreements based on ISO certification and to involve the Authorities at some stage (e.g. validation of certification schemes).

5. Report on the meeting of 25 October 2012 with EDA (European Dairy Association)

BTO report of E6 meeting with EDA (25/10/2012)

Present: EDA, EUCOLAIT and Danish Agriculture and Food Council representatives.

SANCO: C. Bruetschy, J.F. Roche

> EDA represents the EU milk industry. The EU milk sector is shared between cooperatives (60%) owned by farmers and private companies (40%). It is the milk industry which defines the standards and criteria applicable to milk quality (direct link to milk price paid to farmers).

1. Trade of milk and milk products

The EU does import very few milk, cream, butter or cheese (less than 1 % of EU production) while EU exports mainly cheese, milk powder and butter. However, the EU imports some high value milk ingredients amongst others from the US: MPC (milk proteins concentrates) and WPC (whey protein concentrates) and lactose. They are intended for incorporation in a large variety of EU milk products or foods (meat products, sport drinks, baby foods) to strengthen the protein content.

2. Milk production

- Reproductive materials

Technical aspects to be discussed with COPA-COGECA.

- Traceability for milk and milk products

At farm level; all the milk is collected in the same tank (no separate collection on a regular basis would be feasible for milk from one or two cows in a herd).

A 30 ton tanker is collecting milk each 1 to 3 days from a series of farmers.

At dairy plant level, usually one storage facility where all the milk collected in a single day is mixed in the same tank(s). New marketing trend for bio milk or grazing cows' milk lead to the splitting of milk storage and processing at the dairy plant level where it is feasible but not at the farm level (specialised in that specific production). This segmentation is possible because of the economic interest (higher milk price) which would not be the case with milk labelled as originating from offspring/descendants of clones.

Therefore, EDA is of the opinion that if EU traceability measures with a separate milk collection at farm and dairy plant would be imposed to the milk obtained from offspring/descendants of clones, then EU dairy farmers would exclude the use of reproductive materials from clones. This would be a fortiori the case if a labelling requirement is also imposed (no market for milk or milk products earmarked as from clones or offspring from clones).

6. Report on the meeting of 5 September and 10 October 2012 with UECBV (European Livestock and Meat Trading Union).

BTO report of E6 meeting with UECBV on cloning issue (5/09/2012 and 10/09/2012)

Present:

UECBV, Dutch and French Federation representatives.

SANCO: C. Bruetschy, J.L. De Felipe, J.F. Roche

UECBV is composed of 56 national federations of meat industry including EEA countries, Croatia, Turquia and Russia. They are competent for meat production (EU slaughterhouses and cutting plants) and imports and exports of meat.

1. Bovines

- **Background: EU production and trade**
  The EU is the **2nd world producer** for **pork meat** (after China) and for **bovine meat** (after USA). EU is **self-sufficient for porcine and poultry** and in **deficit** for **bovine** (3-4%), **ovine** (20-22%) and **horses** (80%) **meat**.
  EU beef production originates **2/3 from milk breeds** (by product of milk production) and **1/3 beef breeds**.
  EU **bovine and ovine meat production decreasing on a regular trend** and **EU consumption** as well. Porcine production is stable but rentability is negative for most farmers.
  EU imports bovine meat from:
  i) South America (mainly Argentine, Brazil, Uruguay) but in significant decrease (local and emerging countries demand is increasing and other competing productions (bio-fuel, feed) severe decrease of cattle production in Argentina partly compensated by Brazil).
  ii) USA mainly with major increase of EU imports (extension of UE import quota in context of new EU-US agreement on hormone free beef production for EU).
  EU exports bovine and pork meat in Russia mainly but also in China, Japan, South Korea and Turkey.

- **Individual identification**
  EU system: Based on double ear tags (electronic identification proposed in Commission legislative proposal which revises Regulation 1760/2000).

  Third countries: no individual identification **except for Australia, New-Zealand (whole production) and Argentina** (for farms which export to the EU).

  For US and Canada feed lots (identification by batch, certification on methods of production (hormone free etc.) before slaughtering. No information on the background and parentage of individual animals before age of 3 to 4 months where they enter into feed lots (A.I. and cloning would also be used for meat breeds such as Hereford and Angus).

- **Reproductive materials**

- **Imports of reproductive materials** quasi exclusively for milk breeds (Holstein mainly), very limited imports for beef breeds (Angus and Hereford in UK / IRL). 90-95% of I.A. for milk production among which around 20% imported from 3rd countries.
- **30% of EU Holstein cattle would have common genetic with US Holstein cattle** (due to imports of reproductive materials from US). The cloning issue (reproductive materials aspects) is in the hands of the EU milk sector (both farmers and milk industry).
- Top list of 50 to 100 US / Canada Holstein bulls with ranking system (on milk quantity, proteins, conformation of animals) with possibility for EU farmers to order directly semen from these bulls.

- **Food products**

- There would be **no market** for beef identified and labelled as derived from clones, offspring and descendants. If EU cloning legislation would set up traceability and labelling measures for those food products, **no products will be labelled in practice as meat from clones/ offsprings/descendants would be excluded from EU production:** It would therefore potentially apply only to beef imports.
- According to NL federation representative, the same objective (EU clone free beef and milk production) could be met through a commitment of all EU operators (farmers and industry) to put in place commercial agreements on a contractual basis with third countries exporters to ensure the importation of "clone free" reproductive materials (and of live animals). This could be done through a **formal commitment of EU farmers and EU meat and milk industry,** as already done in the "Bruxelles declaration" against pig castration practices in the EU (supported by both Council and EP).
- Each food operator has its mandatory traceability system for the labelling of beef origin which is chosen and adapted by each operator depending its needs (slaughterhouse/ cutting plant / retailers).
- Those traceability systems enable to trace back from a steak to a batch of around 20 adult bovines or 100 calves originating from various farms.

2. Ovines and caprines

- Individual identification

  - On paper similar individual identification than for bovines (except electronic identification instead of ear tag). In practice, individual identification for ovine and caprine would not work properly: i) complexity and high costs for electronic identification and ii) many derogations which are foreseen by either EU Regulation (ex < 650.000 ovine for a M.S. such as in Hungary) or decided at national level (derogation for ovine which are directly intended for slaughtering and remain on national territory).

- Reproductive materials

  - No more use of A.I. for ovine and caprine in the EU and therefore no imports of reproductive materials from third countries.

- Food products

  Imports of ovine meat mainly from N-Z and Australia.

7. Report on the meetings of 12 September and 8 November 2012 with COPA-COGECA (European Farmers and European Agri-cooperatives).

BTO report of E6 meeting with COPA-COGECA on cloning issue

(12/09/2012 and 8/11/2012)

Present:

COPA-COGECA representatives.

SANCO: C. Bruetschy, J.L. De Felipe, J.F. Roche

1. Bovine

The general problem is that there is no harmonized EU statistics, but rather information from single countries, which is not collected in the same way. In addition, it shows a large variation with respect to the requested figures or indicators.

Use of A.I. and embryo transfer

- High level of A.I. (around 90%) in main producing countries for bovine milk production while only 20 % for bovine meat production (in NL it is 40 %).
- For beef production, use of A.I. is limited to multiplication farms (breeding programs) and not use by meat production farms. The reason for that is that AI is rarely used for beef cows is that they are outside for most of the year and thus not accessible for the farmer or the AI technician.
- EU average of 10-15% of imported bovine semen (would be up to 40 % in U.K. / NL for Holstein breed) mostly managed by European subsidiaries of US / Canada breeding companies.

Overall imports of the EU-27 have been about 9.7 millions doses in 2011 (Eurostat). A large share is traded between Member States, showing the increasing collaboration between breeding organisations in different Member States, e. g. Germany and Austria, the Netherlands and Belgium or Denmark, Sweden and Finland.)

Semen marketed in the EU by US breeding companies would not be from clones (commercial agreement) but this commercial agreement has not been confirmed by competent professional organisations.

- No statistics on national production nor on intra-CE trade of semen: data are kept by the semen centres; however, data on the use of semen at national level are collected by national professional organisations but only for some Member States and not in a harmonised way.
- There is no EU statistics, Eurostat also provides figures for intra-Union trade; however these do not always look reliable as you can find big discrepancies between the imports of country A from country B compared to the exports of country B to country A although the figures should be roughly the same.
- Data on Traces are different and lower than those from Eurostat (1.8 Million doses of imported bovine semen compared to around 10 Million doses for Eurostat). This results mainly from the lack of harmonisation of the

registration of semen doses (by kg, by volume, by number of doses etc.) by the competent Authorities at EU Border Inspection Posts where the primary objective is to control the compliance with EU animal health and zootechnical legislation.

- **WHFF guidelines (Holstein breed) on cloning (2006)** requires that:
    - name of cloned calf = name of original animal followed by number 2 (2.1; 2.2 etc.).
    - semen from clones and embryo obtained by cloning technique should bear a suffix ETA /ETN for their identification and registration.
    - it is important to note that the identification of the source animal should be recorded, too, and that each breed association should establish its own procedure relating to the registration of progeny of clones.

- **EU Breeding organisations**

- Semen centers and breeding organisations are either cooperatives or private companies: relative importance between the 2 types of actors varies depending Member States.
- Use of embryo transfer in breeding programs only: to obtain mothers which will produce reproductive bulls (100% genetic under control with embryo transfer while only 50 % with semen).
- Management by milk/meat performance organisations with computing centres. Assessment of breeding value based on several criteria (health, milk, meat, fertility, longevity, functional traits etc.)
- All breeding bovines in semen centres are registered in herd books as well as pure bred bovines from production farmers (to be supplied only with approved semen).

- Milk farmers produce and sell calves to meat producers of calf meat and JBB for feedlots (JBB jeunes bovins de boucherie). Milk farmers do not register the pedigree of the calves intended for meat production.

2. Porcine

- A.I. is the rule (100%) for selection / multiplication schemes but also in rapid increase for meat production.

- Very limited imports of semen (frozen semen) and only for selection/multiplication schemes: Use of fresh semen locally produced except for imports.

- Common practice to mix the semen of different reproductors to produce semen doses in order to boost fertility (no parentage traceability). This practice is not done for selection purposes.

- Pork meat production is very competitive and prices are relatively high for the moment, however, feed prices as well, hence margins remain low: no market for "clone free" pork meat.

3. Ovine and caprine

- A.I. is the rule for selection / multiplication schemes.

- Common practice to mix the semen of different reproducers to produce semen doses in order to boost fertility (no parentage traceability).

8. Report on the meeting of 18 December with UECBV (European Livestock and Meat Trading Union).

BTO report of E6 meeting with UECBV on cloning issue – porcine sector (18/12/2012)

Present:

UECBV, Dutch Federation and Pig Research Centre in Denmark representatives.

SANCO : J.F. Roche, J.L. De Felipe

Porcine sector:

Cloning in the porcine sector is not in use in Europe for production purposes. This technique is not needed for reproduction of pigs as there are large litters and a short time interval from one generation of pigs to the next, and the costs of cloning is not justified, either in the nucleus herds or at the production level. This report is therefore more a description on the structure of the pig production, the breeding and reproduction techniques used, like AI, and the trading of pigs in the porcine sector.

The structure of the porcine sector is divided mainly in three levels. The nucleus farms in which the boars and sows are present for genetic distribution, the multiplying farms with sows producing crossbred gilts and finally the production farms for for crossbred production and fattening of the piglets for slaughter.

AI for pigs started in the 70' and since then is done mainly by the farmers using fresh semen. The preservation system of fresh semen has been improved enlarging the life time of semen from 3 to 5 days. Frozen semen is reducing the quality of semen and consequently the litters are small.

The use of AI is generalized and in average the use is >90% in countries like DK and NL. For the selection in the top of the pyramid the percentage even could reach 95%. It is difficult to give a figure for others EU Member States. Embryo transfer technique is not used in the porcine sector. Inseminated sows have 2.3-2.4 litter per year. Mixed semen from 5 different boars is a common practice in the production level in several Member States. This technique has proven to increase the litter size with one-two more piglets per litter. Germany is not using the mixing of semen. Nevertheless, the mixing is never done between boars of different AI centres for sanitary reasons. In case of an animal health problem the blockage of the AI centre has more serious implications than the blockage of the animals at farm or slaughter level. Porcine semen is managed via AI centres, EU approved or not, for international trade or local trade. Boars from the top of the pyramid (breeding herds) are used in average 6-8 months and for boars used at the production level the boars are used during 1 year to 1.5 years (differs from country to country). Breeding values are calculated for all breeding pigs and these values are used for selection of the new generation of breeding pigs.

As regards trade of semen, the practice is not to import or export frozen semen but fresh semen or live boars. A certificate of pedigree (several known generations) and a health certificate usually will accompany this type of trade.

Import of live animals is very limited (Denmark and Netherlands). On the other hand a lot of live females, semen and some boars are exported from these countries all over the world.

At the production level Denmark and the Netherlands are exporting 9.3 (DK, 2012) and 3,8 million (NL, 2012) piglets for fattening per year and Germany is one of the biggest recipients. These piglets are not individually marked and cannot be traced by pedigree, but identified by batch when they leave the farm or the country. Production sows, mainly crossbreds, could be identified at the farm but they don´t have a known pedigree.

Cloning activities in pigs is not taking place in Europe. In Canada, in a research project, a type of transgenic pig has been cloned some years ago to produce a pig with the capability to excrete less phosphorus than ordinary pigs. There is no known activity on cloning for farming purposes in the EU. There is only cloning activities and research going on in the medical humane sector. However, possibilities to evaluate and develop the cloning technique for research could be important for the sector in the future.

The lack of cloning activities in pigs is justified by the short production period for a boar (generation interval could be 400 days for a boar) and the large litters of pigs produced. There is no economic interest to clone specific boars as their production life is so short and the cost of cloning is high. Farmers buy a genetic line more than a specific boar. The genetic lines are adapted to the different type of production and the preferences of the consumers in the different Member States (e.g. more or less fat in the meat).

ANNEX III: CONSULTATION STAKEHOLDERS

1. State of Cloning in Member States – Summary

The following summary contains the information given by Member States that replied to the consultation questionnaire. All 27 Member States have answered.

National Legislation
The Member States do not have special legislation regarding the cloning technique and its use for food production purposes, with the exception of **Denmark**. In Denmark cloning and genetic modification of animals, including import and breeding, is regulated by law nr. 550 of June 24th 2005. Essentially, the use of cloning is subject to an authorisation and it is allowed only when it is of substantial benefit for health and environmental purposes. In addition in the **United Kingdom**, cloning for research purposes is covered by the Animals (Scientific Procedures) Act 1986, but its use for commercial purposes is not regulated. In the **Netherlands**, the Dutch Animal Health and Welfare Law forbids the use of biotechnical techniques on animals, unless the minister decides to grant permission, based on ethical motivations on the purpose of research. In **Finland** cloning is indirectly covered by general law on vivisection and animal welfare and in **Portugal** by law on the protection of animals kept for farming purposes. Finally in **Germany** commercial cloning is indirectly covered by animal welfare and in case of experimental trials permission is required.

Use of cloning for breeding purposes
None of the surveyed authorities reports the use of the cloning technique in breeding of species used for food production purposes, and therefore no country has identification requirements for clones or reproductive material from clones, except in **Germany** where clones are registered as such in herd books and detained in semen centres and whose semen is exported to third countries outside the EU. This semen is neither distributed nor used inside the EU. The products of these cloned animals cannot enter in the food chain.

Information from Germany, received after this consultation, confirms that there are currently no live cloned bulls anymore in Germany. In **France** the technique has been used for the breeding of race horses; a registration system for the identification of horses' birth origin is in place. This system can provide information on the reproduction technique, including cloning. In Spain the technique has been used successfully on bovine only once.

Identification or registration
Member States authorities do not monitor if imported animals or reproductive material originates from cloned animals; in most cases it is thus not possible to know whether there have been any imports of cloned animals or reproductive material from clones. The exception, again are the cases of Germany of clones of elite bulls who are registered in herd books and their semen is marketed in third countries and the race horses in **France**, which have a specific registration system (SIRE/Haras nationaux).

Animal health and welfare
No information about improvements in the health and welfare conditions of animals used in cloning is known to any Member State competent authority. An "Opinion on the Welfare implications of Breeding and Breeding Technologies in Commercial Livestock Agriculture"

has been published in November 2012 by the United Kingdom Farm Animal Welfare Committee. No improvements in the health and welfare of animals are mentioned.

Scientific risk assessments

The **French national agency for the safety of food, environment and work** (ANSES) has published a report in September 2005 on the risks and benefits related to cloning. This assessment is mainly focus on Bovines, descendants of clones are considered as similar as the animals obtained by traditional reproduction techniques and due to the reduced data it suggested to perform more analysis and collection of data during several generations.

The Board of the Food Standard Agency in the **United Kingdom** asked the Advisory Committee on Novel Foods and Processes to conduct a hypothetical assessment of an application of food from cloned animals (cattle and pigs) under the EU Novel Food Regulation 258/97/EC. The main conclusions were that: no differences in composition between meat and milk of conventional animals and clones and their progeny, which is therefore unlikely to present any food risk; the data on composition are limited and more evidence is required on how different environments may affect the meat and milk; any potential differences between conventional cattle and the progeny of a clone were unlikely to exist from the second generation onwards and finally consumers may want to see effective labelling of products from clones and their offspring.

Other Member State authorities base their opinion on the EFSA scientific documents.

Research

Cloning is used for research purposes in the **Czech Republic**, **Denmark**, **Estonia**, **France**, **Germany**, **Italy, Spain** and the **United Kingdom**. In the **Czech Republic** studies focus on processes of reprogramming of transferred nuclei – epigenetic modifications. In **France**, research focused on the technique itself, on the development of cloned animals and to study the contribution of epigenetic to the variability of phenotypes in cloned animals. In **Italy** one company is working on cloning with pigs for humane health purposes. In **Spain** research is pursued with the purpose of improving the SCNT technique itself, of using pigs for human disease research and for animal species preservation.

See summary table below.

Country	National legislation	Use of cloning	Identification of clones	Identification of Rep. Materials	Imports of clones or Rep.Materials	Identification of imported clones or Rep. Materials	Improvements on animal health	Risks assessment	Cloning for research
Austria	No	No	No	No	No	No	No	No	No
Belgium	No	Yes for horses. Unknown for other species	No official registration. AWE foresees a code at the end of the name. None have been registered.	No	Yes for horses Unknown for other species	Yes for live horses. Imported horses have specific identification with a Greek letter in their name registered in the Studbook.	No Unknown for horses	No	No
Bulgaria	No	No	No	No	No	No	No	No	No
Cyprus	No	No	No	No	No	No	No	No	No
The Czech Republic	No	No	No	No	No	No	No	No	Yes, at the Institute Animal Science and the Institute Animal Physiology and Genetics
Denmark	Yes, Law on cloning and genetically modification of animals, law nr. 550 of June 24th 2005.	No A permission is needed for research purposes	All cloned animals produced following the research permission are identifiable by registration of the animal. Imported cloned animals, who are regarded to be few, are not registered.	No	Unknown	No	No	No	Yes, at the University of Aarhus
Estonia	No	No	No	No	Unknown	No	No	No	Yes
Finland	Indirectly through legislation on animal welfare and animal testing. Cloning not specifically mentioned.	Unknown	No	No	Unknown	No	No	No	No

Country	National legislation	Use of cloning	Identification of clones	Identification of Rep. Materials	Imports of clones or Rep.Materials	Identification of imported clones or Rep. Materials	Improvements on animal health	Risks assessment	Cloning for research
France	No	Yes. Only one company that breeds horses for sport purposes is known to the authorities	Yes. Only for horses bred for use in sports (SIRE/Haras nationaux).	No	Unknown	No, except for horses	No	ANSES report on the risks and benefits related to cloning by (2005)	Yes, at the National Research Institute for Agriculture (INRA)
Germany*	No Legislation on animal welfare. Permission for experimental trials.	There are currently no live cloned bulls in Germany	No, but they are registered in herd books. It is not possible to give exact figures on the number of clones.	No	Unknown	Unknown	No	No	Yes, at the Friedrich-Loeffler-Institut (FLI)
Greece	No	No	No	No	Unknown	No	No	No	No
Hungary	No	No	No	No	No	No	No	No	No
Ireland	No	No	No	No	No	No	No	No	No
Italy	No	No	No	No	No	No	No	No	Yes, the genetic center AVANTEA on pigs for humane health purposes
Republic of Latvia	No	No	No	No	No	No	No	No	No
Lithuania	No	No	No	No	No	No	No	Yes (EFSA assessments)	No
Luxembourg	No	No	No	No	Unknown	Unknown	No	No	No
Malta	No	No	No	No	Unknown	Unknown	No	No	No

***Information received from Germany after this consultation confirms that there are currently no live cloned bulls in Germany**

Country	National legislation	Use of cloning	Identification of clones	Identification of Rep. Materials	Imports of clones or Rep.Materials	Identification of imported clones or Rep. Materials	Improvements on animal health	Risks assessment	Cloning for research
The Netherlands	Indirectly through the Dutch Animal Health and Welfare Law. Special permission for research purposes	No	No	No	Unknown	No	No	No	No
Poland	No	No	No	No	No	No	No	No	No
Portugal	Indirectly through protection of animals kept for farming purposes (Dir 98/58)	No	No	No	No	No	No	No	No
Romania	No	No	No	No	Unknown	Unknown	No	No	No
Slovak Republic	No	No	No	No	Unknown	Unknown	No	No	Yes (In cooperation with INRA)
Republic of Slovenia	No	No	No	No	No	No	No	No	No
Spain	No	Not currently	No	No	Unknown	No	Yes (Article from 2008)	No	Yes, Universidad Autónoma de Barcelona, University of Murcia, Research and Agroalimentary Technology Center of Aragón (C.I.T.A.)
Sweden	No	No	No	No	Unknown	No	No	No	No
United Kingdom	Only for research purposes through the Animals Act (Scientific Procedures) 1986. Commercial SCNT is not covered by the Act.	Unknown	No	No	Unknown	No	No. Report by the Farm Animal Welfare Committee. No improvements are mentioned	Yes.	Yes. Not possible to disclose this information obtained in the course of functions under the Animal Act of 1986.

2. State of Cloning in Third Countries – Summary

The European Union trades with partner countries in sectors that are relevant to the cloning technique. Fifteen countries were consulted, based on two main criteria: the countries which carry out cloning activity and, in addition, the main exporters of meat and reproductive materials to the EU Third Countries (Argentina, Australia, Botswana, Brazil, Canada, Chile, China, Japan, Namibia, New Zealand, Norway, Paraguay, Uruguay, United States and Switzerland). The following summary contains the information given by the government authorities of Third Countries that replied to the consultation questionnaire. 13 third countries have answered. China and Chile did not reply to the questionnaire. For the USA, information provided from the public authority was complemented with information given from private companies to the Commission.

Some third countries which together supply the majority of livestock-product imports of the European Union made a Joint Statement on animal cloning for livestock production signed by Argentina, Brazil, New Zealand, Paraguay and the United States of America on 16 March 2011 a second one on 26 October 2012 signed by the same countries except Paraguay.

The main points identified in this statement are the following:

-Regulatory approaches should be science based and no more trade-restrictive than necessary to fulfil legitimate objectives,
-No evidence indicating that food from clones or the progeny of clones is any less safe than food from conventionally bred livestock,
-Progeny of clones are the same as any other sexually-reproduced animal of their own species,
-Restrictions on food from progeny of clones could have negative impacts on international trade and
-Any audit or enforcement measure on progeny of clones would be impossible to apply legitimately and would results in onerous, disproportionate and unwarranted burdens on livestock producers.

National Legislation

Most authorities have stated that they do not have specific legislation governing the use of animal clones, with the exception of Norway in which the animal cloning is forbidden by law. Animal clones, their progeny and products deriving from animal clones are subject to the same regulations as conventional animals regarding food safety, animal health and animal welfare. Regulations on the use of animals for research purposes also apply.

In most third countries, food from clones is not considered to be different from food derived from conventional animals, based on the assessment of the risks of consumption of food derived from clones (see below).

An exceptional case is Canada, where food from clones and their progeny falls under the novel food definition and, as such, it requires a pre-market safety assessment. Animal feed that derives from clones and their progeny is also considered novel feed, which has to be notified for assessment to the Canadian Food Inspection Agency prior to introduction to the feed chain. Finally, SCNT animal clones, their progeny and their products and by-products are considered new substances under the Canadian Environmental Protection Act and

manufacturers or importers of such substances must notify it to the Minister of the Environment.

In Japan, the Ministry of Agriculture, Forestry and Fisheries has imposed a voluntary ban on the use of cloning for livestock animals except for research purposes.

In Australia there is an explicit industry moratorium on products of cloning entering the food supply.

Brazil is in the process to set up legislation on cloning. The Brazilian Senate draft proposal is regulating the activities of research, production, import and sale of cloned animals. This project will go to the House of Commons to be analysed. The main purpose of the project is to provide a legal framework of the animal cloning activity already in place in Brazil, including research, and strengthen the official control.

Use of cloning for breeding purposes

Cloning is used for breeding purposes in Australia, Argentina, Brazil and the USA. However, since cloning is not regulated in any of these countries, authorities do not have specific information about these activities.

In Canada, no companies of which the government is aware are currently using cloning with the purpose of breeding animals for the commercial livestock sector. One company operates a laboratory for the purpose of harvesting elite performance horse embryos for use in cloning but the embryos are exported and not brought to term in Canada.

In December 2011, US private companies that engage in cloning have provided the Commission with the following data for the number of clones of different species: 1100 bovines, 190 pigs, more than 100 horses. Cloning of goats was just starting, while no sheep had been cloned so far.

Identification or registration

In most of the countries examined clones are not distinguished and registered separately from conventional animals.

In Canada registration of cloned animals is voluntary. Some livestock breed registries have provisions to identify animal clones through a supplemental designation on the registration documents. Semen and embryos are collected, identified and transferred in accordance with protocols established by the Canadian Embryo Transfer Association. The documentation for semen and embryos must identify animal clones through a supplemental designation on the registration documents.

In the USA, public authorities do not require clones to be distinguished from conventional animals. However, private companies have set up a supply chain management system for livestock, whereby animals are registered. Cloned animals are individually identified and registered by private companies. For reproductive materials (semen and embryo), it is up to each breeding centre to decide whether to identify, or not, material from cloned animals.

In New Zealand, the New Zealand Food Safety authority adopted a regulated control scheme, which applies to all ungulate animals. Under this scheme, owners of cloned animals must provide the Ministry of Agriculture and Forestry with a statement that provides information

that allows identification of the cloned animal and registration in an official database. This measure is intended to facilitate access to foreign markets should an importing country introduce restrictions relating to products derived from clones. There are currently 13 cloned animals in New Zealand, most of which are owned by the Crown Research Institute.

In Brazil, cloned animals are registered via the breeding organisations, but the public authority does not keep this information.

The Japanese Ministry of Agriculture, Forestry and Fisheries keeps records of the number of cloned livestock. The cumulative number of cloned cattle produced in Japan until 2011 is 591 cattle, 609 pigs and 9 goats.

Imports

Most government authorities said they do not have information on the nature of live animals or reproductive materials that are imported in their countries. Whether such imports are live clones or reproductive material from clones is thus unknown.

In Canada a pre-import notification is required to import clones and their reproductive material, but at this time no notification was submitted to government authorities. No country has a system of identification and registration in place for such imports.

Animal welfare

Argentina cited several papers as evidence of improvements of the animal welfare implications of cloning. In their experience of Argentine cloning techniques are not different from other assisted reproduction techniques in use worldwide. So, in no case animal welfare can justify any trade restrictive requirement.

FDA recently submitted to EFSA its most recent bibliography on scientific papers addressing this issue. The newer data all support that the risks of health and welfare appear to be quite low.

Scientific risk assessments

Studies on the risk of consuming food derived from clones and offspring has been carried out by scientists in several countries and are often the basis on which third country authorities form their opinions.

USA, Canada, Switzerland and Japan have carried out their own risk assessments. All these risks assessments, except the one from Japan, include also considerations on risks posed on animal health.

Traceability and labelling

No country has traceability and labelling systems for food derived from cloned animals and/or their offspring in place. Switzerland, however, considers that this could be an option for future action.

Research

Research on cloning is pursued in all countries except Paraguay, Namibia and Botswana, but authorities do not have detailed information on it. In Canada, animals used for research purposes are explicitly prohibited to enter the food chain or be released into the environment. In New Zealand, research is pursued by AgResearch Limited (a Crown Research Institute), which has an explicit voluntary moratorium preventing products derived from cloned animals they own entering the food chain. In Japan, research on the SCNT is promoted by the authorities competent for the improvement and increased production of livestock.

See summary table below.

Country	National legislation	Use of cloning	Identification of clones	Identification of Reprod. Materials	Imports of clones or rep.mat.	Identification of imported clones or rep.mat.	Improvements on animal health and welfare	Risks assessment	Traceability and labelling of clones and offspring	Cloning for research
Argentina	No. Indirectly through animal welfare legislation applicable to animals used for scientific purposes.	Yes	No	No	Unknown	No	Yes Papers cited	Yes Papers cited	No	Yes, but detailed information is not available
Australia	No	Yes + voluntary moratorium on products of cloning entering the food supply.	No	No	Yes. But no Government register.	No	No	No	No	Yes but detailed information is not available. Cloning is covered by national animal research guidelines.
Botswana	No	No	No	No	No	No	No	No	Yes	No
Brazil	No. A draft proposal initiated by the Senate regulating the activities of research, production, import and sale of cloned animals in under discussion.	Yes	Yes, the cloned animals are registered via breeding organisations	No	Unknown	No	Unknown	No	No	Yes but detailed information is not available

Country	National legislation	Use of cloning	Identification of clones	Identification of Reprod. Materials	Imports of clones or rep.mat.	Identification of imported clones or rep.mat.	Improvements on animal health and welfare	Risks assessment	Traceability and labelling of clones and offspring	Cloning for research
Canada	No. Cloning falls under Novel food legislation. Products or by-products of any animal clones or their progeny to the human food supply are subject to a pre-market safety assessment.	Yes. A few bovine artificial insemination centres in the past but euthanized since then. No entry into the food chain. One company haversting elite performance horse embryos for use in cloning and exported before the end of the process.	Yes. Some Canadian livestock breed registries have voluntary provisions to identify animal clones through a supplemental designation on the registration documents. Holstein Canada has special protocols for recording clones.	Yes. Documentation for semen and embryos must identify animal clones through a supplemental designation on the registration documents.	Unknown. Pre-import notification requirement. At this time, no pre-import notification submitted to government authorities.	No	No	Yes, draft scientific opinion for internal reference only.	No	Yes, but such animals do not enter the food chain
Japan	No. The Ministry of Agriculture had imposed a voluntary ban to research institutes on the use of cloning except for the purpose of research.	No	Yes. All cloned animals in the research Institutes are notified to the public authority and registered. Carcasses of cloned animals after research are incinerated or buried properly.	Yes. Research Institutes control reproductive materials and after use for research they shall be disposed properly by incineration or burial.	Unknown	No	Unknown	Yes, only on the risks of consuming food derived from clones (June 2009). No assessment has been conducted from the point of view of animal health and welfare.	Yes, for animals used in Research Institutes. Products from clones have to be disposed after use for research by incineration or burial. No for offspring of clones	Yes

Country	National legislation	Use of cloning	Identification of clones	Identification of Reprod. Materials	Imports of clones or rep.mat.	Identification of imported clones or rep.mat.	Improvements on animal health and welfare	Risks assessment	Traceability and labelling of clones and offspring	Cloning for research
Namibia	No	No	No	No	No	No	No	No	No	No
New Zealand	No. Indirectly, market access of food derived from clones and their progeny and welfare implications for cloned animals are covered by general legislation.	No	Yes. Regulated control scheme requiring cloned livestock to be identified with an ear tag unique to each animal and listed in an official database.	No	Unknown	No	No	Yes,A based on relevant scientific external evidence	No	Yes, it is pursued by AgResearch Limited (a Crown Research Institute), which has a voluntary moratorium preventing products derived from cloned animals they own entering the food chain.
Norway	Yes. Cloning is forbidden by law. Exception for research.	No	No	No	No	No	No	No	No	No
Paraguay	No	No	No	No	No record.	No record	No	No	No	No
Switzerland	Yes, Legislation on animal experiments applies needing a licence from the cantonal authorities.	No	No	No	Only once in 2005 of semen from a bull whose mother was cloned, none since. 200 live cattle with a cloned cattle in the pedigree.	No	No	Yes, studies relate to animal health and welfare, food safety and ethical considerations.	No, but setting up a traceability and labelling system for cloned animals and their direct offspring is one option discussed for future action.	Not for farm animals. More information in life sciences (animal experimentation) is not available.

Country	National legislation	Use of cloning	Identification of clones	Identification of Reprod. Materials	Imports of clones or rep.mat.	Identification of imported clones or rep.mat.	Improvements on animal health and welfare	Risks assessment	Traceability and labelling of clones and offspring	Cloning for researc
Uruguay	No	No	No	No	Yes	No	No	No	No	Yes in vitro fertilisation. No results on live clones yet
USA	No. Same regulations apply as to conventionally-bred animals with respect to animal care and welfare, treatment with animal drugs, and introduction into the food/feed supply.	Yes	No. However, there is an industry-sponsored supply chain management system for livestock, to track clones.	No	Unknown	No	Yes, FDA recently submitted to EFSA its most recent bibliography on scientific papers addressing this issue. The newer data all support that the risks of health and welfare appear to be quite low.	Yes, FDA scientific opinion.	No	Yes, but detailed information is not available

3. Stakeholders position

In addition to the participation in the IPM public consultation, the main sectors concerned by the animal cloning have also provided their position paper on this issue. The different position papers from European farmers to the European consumer association are summarized below.

a. Farmers and breeding sector

COPA-COGECA as EU representatives of farmers and agri-cooperatives consider that any measure on animal cloning should be Science-based, cost-effective and workable in practice. They are also concerned about the possible indirect impact on European farmers of a ban of food from cloned animals since several third countries do not have traceability systems in place. Copa-Cogeca considered that traceability of clones may not be problematic but imposing a traceability scheme to offspring represents a real administrative burden for all the supply chain without benefits for the consumers. They would rather favour voluntary information schemes.

BAB (British Agriculture Bureau**)** feels that is inappropriate to ban a technology in food production when there is no scientific basis for a food safety risk, as confirmed by the European Food Safety Authority (EFSA). The UK farming unions believe option 1 is the preferred option and importantly the most scientifically sound option in light of the EFSA opinion that there are no food safety issues with the offspring from cloned animals.

EFFAB (European Forum of Farm Animal Breeders**)** strongly supports maintaining the status quo. EFFAB believes that any measures must be based on sound scientific evidence and enforceable not only by EU member States but also by third countries. They also considered that the adverse effects of cloning technology are limited at present and will reduce with further developments. They also share the view of EFSA and the USA Food and Drug Administration (FDA) where current evidences suggests that meat and milk for healthy clones or healthy offspring of clones is as safe as that from conventional healthy animals.

EAAP (European Association for Animal Production**)** and **ICAR** (International Committee for Animal Recording**)** expressed the interest of both organisations in supporting the research in animal cloning, independently from the concerns that the European consumers may express in other forums. Even if the use of cloning in animal production is limited certainly their medical applications appear to be promising. Both organisations support clone research, to allow the European scientists may retain the necessary tools and knowledge to achieve beneficial goals.

The **IETS (**International Embryo Transfer Society**)** and the **INRA** (Institut National de la Recherche Agronomique**),** both from scientific area, considered that more research in the cloning process and in the animal health issues needs to be encouraged. The IETS has issued a set of guidelines based on scientific knowledge of research teams to lower the incidence of neo-natal concerns. Concerning food safety and labelling aspects, the IETS considered that based on EFSA and U.S. FDA scientific opinions concluding on the lack of evidence of food safety concerns for food derived from clones or offspring, there is no necessity to label such food.

The **FVE (**Federation of Veterinarians of Europe**)** stated that there is no evidence that food safety is adversely affected, but the public are concerned for ethical and other reasons such as poor welfare due to a focus on agricultural productivity, a reduction in genetic diversity and environmental impact.

b. Food industry

The dairy association **EDA** (European Dairy Association) and **EUCOLAIT** (European Association of Dairy Trade) both supported the status quo for which a pre-market approval for food from clones is necessary. Offspring first generation and descendants are considered as conventional bred and not distinguishable from any other animal of the same species and therefore cannot be considered clones. They also based their position in the EFSA conclusions and recommendations of 2008 followed by their statements of 2009, 2010 and 2012 in which the safety of food from clones and progeny are not different to those from conventionally bred animals.

The European meat sector via **UECBV** (European Livestock and Meat Trades Union) and **CLITRAVI** (Liaison Centre for the Meat Processing Industry in the EU) provided also their positions. In both cases the support the status quo. In their view the EU policy on cloning should be based in sound science, practicality to implement identification traceability and labelling of animals and food and public concerns should be taken into account in a balanced and proportionate manner. They also suggested in order to prevent misinformation and unfounded public concerns the implementation of appropriate information campaigns to explain the issues to the public. Another key point of concern for the meat industry is the potential trade disruption with important trade partners like USA, China, Canada, Brazil and Japan.

Food Drink Europe organisation (EU food industry) is in favour to take measures (identification, traceability and labelling) only on clones which are already included in the current Novel Food regulation via the pre-market authorisation of food from clones. They are against to take measures on offspring and descendants of clones based on that there are no food safety concerns. In the other hand FoodDrink Europa is in favour of the traceability of reproductive materials from clones to be able to monitor the animal health and welfare of the offspring of clones.

CELCAA (Agricultural trade) considered that a complete ban or a mandatory labelling system of food both from clones and their offspring based solely on ethical considerations would be completely disproportionate in light of its uncontrollable economic impact and therefore very difficult to justify. Furthermore, traders question the feasibility of an effective enforcement of potential bans (as requested in the past by the European Parliament), be it to prohibit imports completely. In addition, the measures would be very difficult to defend within the WTO.

Euro Commerce (Commerce/retail/wholesale sector)
Considered it is necessary to keep up with the continued research progress on animal cloning techniques. Besides scientific data, other legitimate factors, such as ethical considerations need to be taken into account in the decision process. Nevertheless, Euro Commerce has no intention to participate in the ethical debate. They also consider essential to take into consideration the consumer acceptance on this issue in addition to inform the citizens about animal cloning versus genetically modified animals, the benefits, risks and impacts, so that consumers are well informed. If products from clones and offspring of clones are authorised find a practical solution to trace these products along the whole food supply chain.

c. Consumer organisations

BEUC, the European Consumers Organisation, (based on IPM consultation) considered that the current situation does not guarantee a sufficient level of consumer protection as food

derived from offspring or descendants of clones is not subjected to any pre-market authorisation. They state that consumers should have the right to make an informed choice and in this case, that is to decide whether or not they wish to eat food from clones, their offspring or descendants. The Flash Eurobarometer on Europeans' Attitude towards animal cloning (October 2008) found that a majority of EU citizens do not want food derived from cloned animals to enter the food chain. A more recent Special Eurobarometer Survey on Food-related Risks (November 2010) also showed that cloning animals for food production is one of the most widespread food safety-related concerns of Europeans consumers. Finally another recently Special Eurobarometer Survey on Biotechnology (October 2010) showed that Europeans have strong reservations and concerns about the safety of animal cloning for food production.

d. Animal welfare associations

Eurogroup for Animals and **Compassion in World Farming** are the two NGOs who have provided a position paper on this matter. Both consider that cloning technique is inefficient and involves severe animal suffering linked to health and welfare problems for cloned animals and their surrogate dams. In addition, the routine use of cloning would reduce genetic diversity and increase productivity with insufficient attention to the animal welfare. Finally they also underline the well-documented public concerns related to the use of cloning for food production purposes.

In summary, both professional organisations of the farming, breeding and the food sectors are in favour of the status quo. They do not support the ban of cloning technique as they consider that this technique may improve and could be important in the future for the competitiveness of the EU farming and breeding sectors. They are also against any labelling measures concerning food from offspring or descendants as there are no food safety concerns and such measures would entail additional administrative burden and costs for operators along the food chain. On the other hand, consumer and animal welfare organisations are in favour of a ban of the cloning technique in the EU and of mandatory labelling for food from offspring and descendants to provide consumer choice.

4. Third country competent Authorities

Consultations with main trade partner third countries competent authorities (Argentina, Australia, Botswana, Brazil, Canada, Chile, China, Japan, Namibia, New Zealand, Paraguay, Switzerland, Norway, Uruguay and United States of America) have taken place using a special questionnaire to assess the situation on animal cloning for food production, via bilateral meetings or in some cases using the IPM public consultation. Most of the authorities do not have specific legislation governing the use of animal cloning for food production. Animal clones, their progeny and products derived are subject to the same regulations as conventional animals regarding the food safety, animal health and welfare.

Japan has imposed a ban on the use of cloning for livestock animals and Australia and New Zealand have an explicit industry moratorium on products on cloning entering in the food chain.

Some third countries which together supply the majority of livestock-products which are imported in the European Union made a Joint Statement addressed to the Commission on animal cloning for livestock production signed by Argentina, Brazil, New Zealand, Paraguay and the United States of America on 16 March 2011 a second one on 26 October 2012 signed by the same countries except Paraguay.

The main points identified in this statement are the following:

- Regulatory approaches should be science based and no more trade-restrictive than necessary to fulfil legitimate objectives,
- No evidence indicating that food from clones or the progeny of clones is any less safe than food from conventionally bred livestock,
- Progeny of clones are the same as any other sexually-reproduced animal of their own species,
- Restrictions on food from progeny of clones could have negative impacts on international trade and
- Any audit or enforcement measure on progeny of clones would be impossible to apply legitimately and would results in onerous, disproportionate and unwarranted burdens on livestock producers.

ANNEX IV: IPM SUMMARY REPORT AND ORIGINAL QUESTIONNAIRE

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

CONSULTATION ON ANIMAL CLONING FOR FOOD PRODUCTION

SUMMARY OF THE REPLIES TO THE IPM CONSULTATION

This document does not represent an official position of the European Commission. The suggestions contained in this document do not prejudge the form and content of any future proposal by the European Commission.

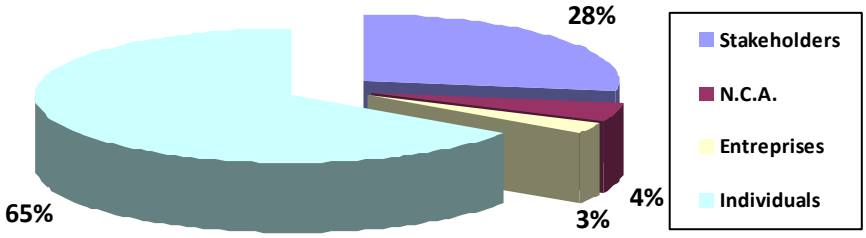
INTRODUCTION

On 3 May 2012 the European Commission launched an IPM public consultation on animal cloning for food production. This consultation sought to gather the views and opinions of all interested parties on various aspects surrounding the issue of cloning for food production, such as the use of the cloning technique, the use of clones and their reproductive materials (semen and embryo) for breeding purposes and the use of live clones, their offspring and descendants for food purposes.

It targeted companies, organizations with an interest in the matter, experts in the field as well as ordinary citizens. The consultation was open online for 16 weeks (from 03.05.2012 until 03.09.2012). Reminders were done by the DG Health and Consumers using its website (Flash news) and via the e-news network on 4 July 2012 reaching approximately 6000 subscribers. Another reminder was also launched on 21 June 2012 using the Enterprise Europe Network (EEN). The consultation period ended on 3 September 2012.

The Commission received 360 replies (56 requesting confidentiality, 150 anonymously and 154 under the name indicated):

- 99 Stakeholders (Professional Organisations, NGOs, International organisations and Academic).
- 16 from National Competent Authorities (NCA), IRL(2), UK, AT, FIN, DE, CZ, PT(2), FR, LX, IT and ARG (4).
- 9 from enterprises, including 7 from SMEs (including 2 micro enterprises) and 2 large enterprises.
- 236 from individual persons (209), self-employed (17) and others (10).



This document summarises the responses to the public consultation on the possible measures on animal cloning for food production. It is in no way to be understood as an endorsement of any comment. For the sake of brevity, consultation items are not reproduced. Therefore, this summary should be read in conjunction with the original questionnaire and the roadmap on animal cloning for food producing published in February 2012[1]

[1]http://ec.europa.eu/governance/impact/planned_ia/docs/2013_sanco_007_use_of_cloning_technique_for_food_production_en.pdf

In addition, main comments of position papers received from stakeholders organisations are also mentioned in chapter 3.

The public consultation is part of the on-going impact assessment exercise. The information and views gathered in this public consultation will be taken into consideration in the impact assessment process.

GENERAL REMARKS

The public consultation was appreciated by the stakeholders with an acceptable participation. The vast majority of respondents 72.5% were well informed on the subject animal cloning for food production and also a large majority 68.6% considered that the current situation is inappropriate and need to be changed. Based on the participation distribution mentioned above, some cautions needs to be exercised when drawing conclusions from these figures as all the different categories from individual to professional organisations or international organisation have the same value as a single record even if the stakeholder organisations are representing a group of persons.

The majority of the respondents were in favour of a ban of the animal cloning covering all the different areas such as the cloning technique, the use of live cloned animals, clone reproductive materials, live offspring and descendants of clones and the food derived. The most important reason was the animal health and welfare.

Concerning the pre-market approval of food from clones, offspring and descendants of clones the majority of the respondents were in favour of such pre-market approval given the food safety concerns as the most important reason to put in place this measure. In the other hand the most important reason against a pre-market approval was also the no food safety concerns.

It is important to underline that for some areas such as placing food from clone origin on the market and pre-market approval there was a slight decrease in the percentage for the descendants of clones in relation to the clones.

The majority of the respondents were in favour of the identification and registration of clones, reproductive materials of clones and offspring and descendants of clones. In this case also there was a slight decrease in the percentage from the clones (86.91%) to the descendants (71.9%). The most important reason in favour to set up this identification and registration system was the possibility to monitor the animal health and welfare. In the other hand the most important reason against to set up this system was that this measure is not based on science.

Similarly to the previous areas the majority of the respondents were in favour of a traceability system for food from clones and offspring and descendants of clones. Again the percentages in favour are decreasing from 88.6% for clones to 71.9% for descendants of clones. The majority of the respondents (79.2%) considered that the traceability system can be established and the cost should be bear by the food industry (60.3%) covering all the species (cattle, pigs, horses, goats and sheep).

The consumers' information based on labelling schemas was supported by a majority of the respondents using a mandatory approach. Again there was a decrease in the percentages for the clones (82.2%) to the descendants of clones (71.1%). The majority of the respondents

considered that all the products proposed need to be labelled and the cost will be mainly bear by the food industry (42.8%).

Finally, concerning the proposed 5 options nearly half of the respondents (49.2%) were in favour of option 5 on a suspension of the use of the cloning technique in the EU, the use of clones and live offspring of clones, the reproductive material from clones and the placing on the market of food from clones and their offspring and descendants. The options 1, 2 and 4 got approximately 10% and option 3 got 5%. The remaining 15% did not select any of the options proposed.

SUMMARY OF RESPONSES (ALL RESPONDENTS)

Awareness about the developments on animal cloning for food production

A large majority of respondents were very well (22.2%) or fairly well (50.3%) informed. Only 19.4% and 8.1% were not respectively very well or not at all informed on animal cloning.

1. Use of cloning technique, clones and food from clones

Nowadays the animal cloning technique is allowed and a pre-market approval for food from clones is required in the EU. So far no such authorisation has yet granted or even requested.

A large majority of respondents 68.6% considered that the current situation is inappropriate, 29.7% were in favour to keep the current situation as it is and 1.7% had no opinion.

Ban and pre-market approval of food on the EU market

The ban on animal cloning is covering the cloning technique, live cloned animals for breeding purposes, clone reproductive materials, live offspring and descendants of clones and the food derived.

Concerning the ban the respondents replied the following:

Ban	In favour %	Against %	No opinion %
Cloning technique	65.5	26.9	7.5
Live cloned animals	71.9	21.1	6.9
Clone reproductive materials	67.2	26.4	6.4
Offspring of clones	69.2	25.8	5
Descendants of clones	68.9	26.4	4.7

For all areas concerning the ban, there were a majority of respondents from 65.5 to 71.9 % in favour of the ban on animal cloning.

The most important reason in favour of the ban was animal health and welfare (25.6%) followed by ethical reasons (23.3%), reduction of diversity and genetic variety (17.2%), food safety concerns (15.8%) and the least important reason was the restriction of access to genetic heritage for example via patents (25.3%).

The most important reason against the ban was the no food safety concerns (13.1%) followed by loss of innovation (8.9%), increase of administrative burden and international trade barrier (5.3% both) and higher costs of production and reduction of food supply (4.2% both).

Concerning the placing of food from clones, offspring of clones and descendants of clones the respondents replied the following:

Food	In favour/%	Against/%	No opinion/%
Clones	15.3	77.5	7.2
Offspring	24.4	72.5	3.1
Descendants	25	71.4	3.6

The majority of the respondents were against to put on the EU market food from clones, offspring of clones and descendants of clones (77.5%, 72.5% and 71.4% respectively). It should be noticed that the percentage against the food is slightly decreasing from 77.5% for clones to 71.4% for the descendants.

Regarding the necessity of a pre-market approval for food from clones, offspring of clones and descendants the opinion of the respondents were the following:

Pre-market approval of food	Necessary	Not necessary	No opinion
Clones	78.1	13.1	8.9
Offspring	68.3	23.3	8.3
Descendants	66.1	24.2	9.7

The majority of the respondents were in favour of a pre-market approval for all food from clones, offspring and descendants of clones. It should be noticed that the percentage for the pre-market approval is slightly decreasing from 78.1% for clones to 66.1% for descendants.

The most important reason in favour of a pre-market approval was food safety concerns (26.9%) followed by animal health and welfare (24.7%), ethical reasons (22.2%) and biodiversity and genetic variety (20.3%).

The most important reason against a pre-market approval was the no safety concerns (11.1%) followed by the use of cloning technique should be banned (7.5%), increased administrative

burden (6.4%), loss of innovation (5.3%), higher cost of production (4.2%) and delay in the marketing of the food product (3.3%).

The identification and registration of live clones, of reproductive materials (semen, embryos and ova) and of live offspring would be a prerequisite for the monitoring of animal health and welfare aspects and for the setting up of traceability and labelling systems for food products which are derived.

Concerning the identification and registration the respondents replied the following:

	In favour of identification and registration of	Not in favour of identification and registration of	No opinion
Clones	87.5	6.4	6.1
Offspring of clones	76.9	17.2	5.8
Descendants of clones	73.9	19.4	6.7
Clone reproductive materials	81.4	11.1	7.5

For all areas concerning the identification and registration the majority of the respondents were in favour to set up a specific identification and registration system for clones, offspring, descendants and reproductive materials of clones produced or imported into the EU.

The majority of respondents considered that the way to put in place the identification and registration system for all the areas concerned need to be via a compulsory system. It should be noticed that the percentage for the identification and registration is slightly decreasing from 86.91% for clones to 71.9% for descendants.

The most important reason in favour to set up an identification and registration system was the possibility to monitor the animal health and welfare (from 50% to 61.4%) followed by to allow food labelling (from 46.9% to 52.8%), the farmer knowledge that the animals are cloned (from 43.9% to 50.8%), and to allow targeted recalls of food from the above categories (from 35.8% to 39.7%).

The most important reason against to set up an identification and registration system was that this measure is not based on science. This reason got the higher percentage in all categories.

Regarding the species to be cover by the identification and registration the majority of the respondents considered that all species need to be covered (Cattle 83.9%, Pigs 81.9%, Horses 77.5%, Goats 77.8 and Sheep 80.3%).

2. Traceability

The setting up of EU identification and registration systems for clones, clone reproductive materials, offspring and their descendants would allow the setting up of traceability systems.

Concerning the traceability system the respondents replied the following:

Traceability system	In favour	Against	No opinion
Food from clones	88.6	7.2	4.2
Food from offspring	77.2	16.9	5.8
Food from descendants	76.4	17.5	6.1

The majority of the respondents were in favour of a traceability system for all the categories mentioned. It should be noticed that the percentage for the traceability system is decreasing from 88.6% for clones to 71.9% for descendants.

Concerning the feasibility of this traceability system 79.2% of the respondents considered that can be established, 15.6% not and 5.3% had no opinion. In addition, 29.7% of the respondents considered that this traceability system may lead to unacceptable cost, 54.4% not and 15.8 had no opinion.

Regarding who should bear the traceability additional costs the respondents considered the food industry in 60.3% followed by the farmers 38.6%, tax payers 38.1 ad consumers 28.1%.

Regarding the species to be cover by the traceability the majority of the respondents considered that all species need to be covered (Cattle 94.7%, Pigs 91.4%, Horses 85.3%, Goats 84.2 and Sheep 87.5%).

3. Consumers' information

Traceability systems for food from clones, offspring and their descendants would allow food producers and retailers to inform consumers via labelling. The possible labelling schemas proposed were none, mandatory, voluntary and others.

Concerning labelling the respondents replied the following:

	No labelling	Mandatory labelling	Voluntary labelling of "clone free food"	Others
Clones	6.7	82.2	5.8	5.3
Offspring of clones	16.1	74.7	6.1	3.1
Descendants of clones	16.9	71.1	8.6	3.3

The majority of the respondents were in favour of a mandatory labelling for clones, offspring and descendants of clones. It should be noticed that the percentage for the mandatory labelling is decreasing from 82.2% for clones to 71.1% for descendants of clones.

Concerning the products to be covered by the labelling systems the majority of the respondents, more than 80%, considered that all the products proposed need to be labelled. They also considered in 81.1% that such labelling can be established and that these labelling may no cause unacceptable costs in 59.7%.

Concerning the group of stakeholders would likely more affected for possible additional costs the respondents considered that will be the food industry 42.8%, followed by tax payers 35.6%, farmers 35% and consumers 33.1%.

4. Policy options

The Commission in its roadmap on animal cloning for food production identified in summary the following 5 policy options:

Option 1. Retain the current legal framework

Option 2. Allow the use of the cloning technique in the EU for food production

Option 3. Temporary ban of food from clones in the EU and tracing of imports of clone reproductive materials

Option 4. Temporary ban of food from clones in the EU and imposition of mandatory labelling of food from offspring and descendants

Option 5. Temporary ban of food from clones, offspring and their descendants

The nearly half of the respondents 49.2% were in favour of option 5 followed by none 15% [to be explain looking in detail the replies], option 1 10.6%, option 2 10.3%, option 4 10% and option 3 5%.

SUMMARY OF THE RESPONSES BY CATEGORIES OF RESPONDENTS

- Individual and self-employment

There were 226 responses from individual (209) and self-employed (17). The majority of the respondents were from Finland (36), United Kingdom (32), France (29), Estonia (25), Germany (18), Italy (15), Portugal (13) and Spain (10).

The respondents in this category were very well informed 13.2% and fairly well informed 52.2% and 34.5% were not very well or not at all informed. In addition 73.9% considered that the current situation is not appropriate.

Concerning the ban of the cloning technique, live cloned animals, reproductive materials of clones, offspring of clones and descendants of clones the respondents were in favour of a ban for all areas: cloning technique 73% live cloned 81.4%,reproductive materials of clones 76.1% and offspring and descendants of clones 79.6% in both cases. The main reason expressed by the respondents to be in favour of a ban was the animal health and welfare with a 27.4% and against the ban the main reason was the loss of innovation with 8.8%.

In relation to the placing of food from clones, offspring of clones and descendants of clones in the EU market the respondents were against to allow the placing of food from clones (86.3%) offspring (84.1%) and descendants (83.2%) of clones.

The pre-market approval was considered by the respondents necessary for food from clones in a 88.9%, 76% for offspring of clones and 75% for descendants of clones. The main reason for the pre-market approval was the food safety concern.

The respondents were in favour of the identification and registration of clones with a 87.2%, 84.5% for offspring of clones, 81.9% for descendants of clones and 85.4% for reproductive materials of clones. In case of the setting up of an identification and registration the majority of the respondents were in favour of a compulsory system for clones 87.2%, offspring of clones 83.2%, descendants of clones 80.1% and 82.3% for the reproductive materials of clones. The main reason to put in place this system was to monitor the health and welfare of the animals. In case of identification and registration the respondents considered that all species proposed should be covered.

In respect to the traceability systems for food the majority of respondents were in favour with a 91% for food of clones, 87% for offspring of clones and 86.3% for the descendants of clones.

Concerning labelling the majority of respondents were in favour of a mandatory labelling for food from clones 89% and offspring and descendants of clones 84% and 82.3% respectively.

Finally concerning the choice within the 5 policy options proposed 58% considered that option 5 was the most appropriate.

- Stakeholders organisations (Professional Organisations, International organisations, Academic and NGOs)

There were 99 responses from stakeholder's organisations, 34 Professional Organisations, 34 NGOs, 26 Academic and 5 International organisations.

The respondents in this category were very or fairly well informed 83.9% and considered that the current situation is not appropriate in a 52.5%.

Concerning the ban of the cloning technique, live cloned animals, reproductive materials of clones, offspring and descendants of clones the stakeholders' respondents were in favour of a ban for all areas, 54.5% for the cloning technique, 57.6% for lived cloned animals 55.6% for reproductive materials of clones 53.5% for offspring of clones and 52.5% of descendants of clones. The main reason expressed by the respondents to be in favour of a ban was the problem of animal health and welfare and against the ban the main reason was the no food safety concern.

In relation to the placing of food from clones, offspring of clones and descendants of clones in the EU market the stakeholders respondents were against to allow the placing of food from clones 64.6%, offspring 55.6% and descendants 53.5% of clones.

The pre-market approval was considered by the stakeholders' respondents necessary for food from clones in a 81.8%, for food from offspring of clones 59.6% and descendants of clones with a 56.6%. The main reason for having necessary the pre-market approval was the food safety concern.

The Stakeholders' respondents were in favour of the identification and registration of clones with 89.9%, for offspring of clones 64.6%, descendants of clones 62.6% and for reproductive materials 75.8%. In case of the setting up of an identification and registration the majority of the respondents were in favour of a compulsory system for clones 88.9%, offspring of clones 64.6%, descendants of clones 60.6% and the reproductive materials of clones 71.7%. There was not a clear majority for the reasons in favour or against to put this system in place. The main reason to put in place this system was to monitor of the animal health and welfare. In case of identification and registration the respondents considered that all species proposed should be covered.

In respect to the traceability systems for food the majority of stakeholders' respondents were in favour for food of clones in a 85.9% and food from offspring and descendants of clones in 61.6% for both. In case of identification and registration the respondents considered that all species proposed should be covered.

Concerning labelling the majority of stakeholders' respondents were in favour of a mandatory labelling for food from clones 70.7% and offspring 57.6% and descendants 51.5% of clones.

Finally concerning the choice within the 5 policy options proposed 32.3% considered that option 5 was the most appropriate, followed by option 1 with a 20.2%.

- Entreprises

There were 9 responses under the category of enterprise, 2 of them were large, 5 SME (2 small and 3 medium) and 2 micro enterprises.

The respondents in this category were very or fairly well informed 88.9% and considered that the current situation is not appropriate in a 66.7%.

Concerning the ban of the cloning technique, live cloned animals, reproductive materials of clones, offspring of clones and descendants of clones the enterprise respondents were in favour of a ban for all areas 55.6% except for offspring of clones and descendants of clones with the same percentage 55.6%. The main reason expressed by the respondents to be in favour of a ban was the possible reduction of biodiversity and genetic variety and be against the ban the main reason was the no food safety concern.

In relation to the placing of food from clones, offspring of clones and descendants of clones in the EU market the enterprise respondents were in favour to allow the placing of food from offspring and descendants of clones with a 55.6% but for food from clones the respondent were against with a 66.7%.

The pre-market approval was considered by the enterprises respondents necessary for food from clones in a 88.9%, but the pre-market approval was not considered necessary for food from offspring of clones and descendants of clones in both cases with a 55.6%. The main reason for not having necessary the pre-market approval was the no food safety concern.

The enterprise respondents were in favour of the identification and registration of clones with 100%, for offspring of clones and descendants of clones also in favour with a 55.6% in both cases and for reproductive materials 77.8% were also in favour. In case of the setting up of an identification and registration the majority of the respondents were in favour of a compulsory system for clones 100%, offspring of clones 55.6%, descendants of clones 55.6% and the reproductive materials of clones 77.8%. There was not a clear majority for the reasons in

favour or against to put this system in place. In case of identification and registration the respondents considered that all species proposed should be covered.

In respect to the traceability systems for food the majority of enterprise respondents were in favour for food of clones in a 100% and food from offspring and descendants of clones in 55.6% for both.

Concerning labelling the majority of enterprise respondents were in favour of a mandatory labelling for food from clones 77.8% and offspring and descendants of clones 55.6% in both cases.

Finally concerning the choice within the 5 policy options proposed 55.6% considered that option 5 was the most appropriate, followed by option 1 with a 22.2%.

- National Competent Authorities

16 replies were received under the NCA category. 12 were coming from EU Member States and 4 from third countries. It should be noted that 8 out of 16 did not mention the name of their organisations at all or were regional authorities. The 10 Member States were Ireland(2), United Kingdom, Austria, Finland, Germany, Portugal(2), Czech Republic, France, Luxembourg and Italy. Argentina was the only third country participating four times, one of them without mentioning the name of the organisation and the other three from the same organisation.

The respondents from the Member States National competent authorities were very or fairly well informed 83.3% and considered that the current situation is not appropriate in a 58.3%.

Concerning the ban of the cloning technique, live cloned animals, reproductive materials of clones, offspring of clones and descendants of clones the Member States respondents were 41.7% in favour and 41.7% against.

In relation to the placing of food from clones, offspring of clones and descendants of clones in the EU market the Member States respondents were against to allow the placing of food from clones but for food from offspring and descendants it was equal percentage in favour and against (41.7%).

The pre-market approval was considered by the Member States respondents necessary for food from clones in a 66.7% and for offspring of clones in a 58.3%, but the pre-market approval was for descendants of clones there was an equal percentage in favour 41.7% and against 41.7%.

The Member States respondents were in favour of the identification and registration of clones 91.7%, offspring of clones 75%, descendants of clones 58.3% and reproductive materials of clones 83.3%.

In respect to the traceability systems for food the majority of the Member States respondents were in favour for food of clones 91.7%, 66.7% were in favour for the food from offspring and 58.3% were against the system for the descendants of clones.

Concerning labelling the majority of the Member States respondents were in favour of a mandatory labelling for food from clones and offspring of clones 75% in both cases, in the

other hand 58.3% of the Member States respondents were in favour of no labelling for the descendants of clones.

Finally concerning the choice within the 5 policy options proposed, options 1 and option 5 were considered the most appropriate both with a 25% each.

DETAILS OF RESPONSES BY CATEGORIES OF RESPONDENTS.

The comparative tables below are presented the detailed positions expressed by the different categories than cannot be observed within the above global assessment. For instance contrary to the position of NGOs and individuals in favour of a general ban of the technique and animals derived from clones, the Professional Organisations are in favour of the ban of the cloning technique, live clones and the traceability of reproductive materials of clones but against any measures on the progeny of clones.

Concerning Competent Authorities of Member States it should be noticed that 5 out of 12 replies do not provide the name of the organisation they are representing and Ireland and Portugal replied twice. For all these reasons some cautions need to be exercised when drawing conclusions from these figures. 6 out of 10 are in favour of the status quo. Concerning the general ban there are the same number of Member States in favour than against. The majority are also in favour of the pre-market approval of food from clones (7 out of 10) and offspring of clones (6 out of 10). Competent Authorities of Member States are in favour of the animal identification and registration and the traceability and labelling of clones and their progeny.

Questions	NGOs	PROFESSIONAL ORGANISATIONS	Individuals and self-employed	Member States*
Level of information – Well informed	94.1%	79.4%	65.5%	83.3%
Current situation	88.2% not appropriate	55.9% agree with the current situation	73.9% not appropriate	58.3% agree with the current situation

* The National competent authorities of EU Member States participating in this public consultation were Ireland (2); United Kingdom; Austria; Finland; Germany; Portugal (2); Czech Republic; France; Luxembourg and Italy.

Cloning Technique

Questions	NGOs	PROFESSIONAL ORGANISATIONS	Individuals and self-employed	Member States
Ban of Cloning technique	85.3% in favour	38.2% in favour	73% in favour	41.7% against and 41.7% in favour
Ban of Live cloned animals	91.2% in favour	38.2% in favour	81.4% in favour	41.7% against and 41.7% in favour
Ban of clone reproductive materials	94.1% in favour	52.9% against	76.1% in favour	41.7% against and 41.7% in favour
Ban offspring of clones	91.2% in favour	61.8% against	79.6% in favour	41.7% against and 41.7% in favour
Ban of descendants of clones	88.2% in favour	61.8% against	79.6% in favour	41.7% against and 41.7% in favour

Foodstuff

Questions	NGOs	PROFESSIONAL ORGANISATIONS	Individuals and self-employed	Member States
Placing food from clones	91.2% against	52.9% against	86.3% against	50% against
Placing food from offspring	94.1% against	64.7% in favour	84.1% against	41.7% against and 41.7% in favour
Placing food from descendants	91.2% against	67.6% in favour	83.2% against	41.7% against and 41.7% in favour
Pre-market approval for food from clones	79.4% in favour	79.4% in favour	79.2% in favour	66.7% in favour

Pre-market approval for food from offspring of clones	79.4% in favour	64.7% against	75.7% in favour	58.3% in favour
Pre-market approval for food from descendants of clones	79.4% in favour	64.7% against	74.8% in favour	41.7% against and 41.7% in favour

Animal identification and registration

Questions	NGOs	PROFESSIONAL ORGANISATIONS	Individuals and self-employed	Member States
Identification and registration of clones	97.1% in favour	79.4% in favour	87.2% in favour	91.7% in favour
Identification and registration of offspring of clones	91.2% in favour	58.8% against	84.5% in favour	75% in favour
Identification and registration of descendants of clones	88.2% in favour	58.8% against	81.9% in favour	58.3% in favour
Identification and registration of reproductive materials of clones	97.1% in favour	47.1% in favour	85.4% in favour	83.3% in favour

Traceability and labelling

Questions	NGOs	PROFESSIONAL ORGANISATIONS	Individuals and self-employed	Member States
Traceability of food from clones	94.4% in favour	73.5% in favour	90.7% in favour	91.7% in favour
Traceability of food from offspring of clones	88.2% in favour	58.8% against	86.7% in favour	66.7% in favour
Traceability of food from descendants of clones	91.2% in favour	58.8% against	83.6% in favour	58.3% in favour

Labelling of food from clones	88.2% in favour mandatory	50% in favour mandatory	88.9% in favour mandatory	75% in favour mandatory
Labelling of food from offspring of clones	85.3% in favour mandatory	64.7% against	84.1% in favour mandatory	75% in favour mandatory
Labelling of food from descendants of clones	82.4% in favour mandatory	64.7% against	82.3% in favour mandatory	58.3% in favour mandatory

Options

Questions	**NGOs**	**PROFESSIONAL ORGANISATIONS**	**Individuals and self-employed**	**Member States**
Options	41.2% Option 5	29.4% Option 1	58% Option 5	25% Option 1 and 25% option 5

ANNEX V: EXECUTIVE SUMMARY OF THE ICF-GHK STUDY ON THE IMPACT IN THE EU AND THIRD COUNTRIES OF EU MEASURES ON ANIMAL CLONING FOR FOOD PRODUCTION

Executive Summary

Introduction

This is a summary of a study commissioned by DG SANCO of the European Commission from ICF GHK to inform and support development and appraisal of proposals to regulate animal cloning in the EU. It provides a feasibility and impact assessment of four possible approaches to regulation of animal cloning for livestock in the EU. It includes a description of the use of and concerns about the technique and the outlook for livestock cloning to 2020. It then compares the expected impacts of various measures, specified by the European Commission, through which the four approaches would be implemented. The appraisal covers feasibility, administrative burdens, induced costs, trade-mediated impacts, employment effects, and then impacts on consumers, SMEs and the environment.

There is currently a lack of inter-institutional agreement between the Commission and the Parliament regarding the regulation of animal cloning in the EU. A Roadmap was developed in February 2012 to address this issue. This study will assist the Commission as it prepares an impact assessment of the five options set out in the Roadmap. The four approaches assessed here are:

- A suspension or ban on animal cloning in the EU, including use of the cloning technique, marketing of reproductive materials from clones, marketing of live clones, and marketing of clone offspring, descendants, and the reproductive materials of offspring and descendants.
- Traceability for clone reproductive materials, live clones, their offspring and descendants, their reproductive materials and derived food products.
- Labelling requirements for food products derived from clones, their offspring and descendants, in addition to the traceability requirements.
- Premarket approval requirements for food products derived from clones, their offspring and descendants, in addition to the traceability requirements.

The scope of work includes bovine, porcine, ovine, caprine and equine animals and spans the full breadth of the food supply chain from production to consumption. The study considers the impacts of the four approaches on both the EU and third countries. It does not consider cloning for research purposes, pharmaceutical production or other commercial uses, including sport and leisure or conservation of endangered species or breeds.

ICF GHK acknowledges with thanks the support given to the study by many stakeholders who participated in the consultation and research process.

Context to the study - livestock cloning in the EU and third countries

Scientific and social context of livestock cloning

Commercial cloning is a form of assisted reproductive technology and may be used to replicate ‘high quality’, high value breeding animals. It can increase the number and therefore the availability of animals with superior genetics. Cloning can multiply the number of such animals, but it is not a breeding technique — an animal with desirable attributes can be replicated, but the technique cannot be used to acquire or refine desirable traits.

Commercial cloning is most common in sectors where assisted reproductive technologies are already widely used and where breeding animals carry a particularly high value. Cloning is currently considered to be of greatest benefit in the dairy industry, where larger numbers of high quality animals could increase overall herd milk yield, the availability of stock with disease resistance and other desirable traits associated with milk quality.

Cloning has been used for bovine, porcine, ovine, caprine and equine animals. Its use has been mostly limited to dairy cattle and horses, however, largely due to their high value as breeding animals. Cloning is relatively expensive and has a high failure rate, making it viable only where the prospective returns are worth the investment. The overall success rate of the cloning procedure is less than 10 per cent in bovine animals and between 5 and 17 per cent in pigs. Its use in equine animals is limited to sport horses. Little use of the technique is made for ovine, caprine and porcine animals.

There are animal health and welfare concerns associated with cloning, particularly the higher mortality rate of clones compared with sexually produced animals. A majority of cloned embryos do not develop to term and of those that do, another proportion die during or shortly after birth from a variety of causes. Surrogate cattle dams also have problems including late gestational loss and more difficult delivery. Studies have shown that survival of offspring and descendants of clones is similar to the survival of conventionally bred animals.

Studies carried out on in the EU and third countries on the safety of food products derived from clones, their offspring and descendants conclude that there are no additional risks associated with consuming these products and that there is no increased risk compared to food products derived from conventionally-bred animals.

Nonetheless, research suggests that EU citizens and consumers are concerned about animal cloning, and oppose its use for livestock. The supply chain does not generally perceive investment in cloning to be worthwhile at this time due to consumer concerns, coupled with high costs to use the technique and availability of other assisted reproduction techniques.

A joint statement on animal cloning issued in 2010 by the governments of Argentina, Brazil, New Zealand, Paraguay and the United States observes that regulatory approaches to agricultural technologies should be 'science based' and should not restrict trade more than necessary to fulfil 'legitimate objectives'. It states that there is no basis to differentiate offspring or descendants of clones from other sexually reproduced animals. New Zealand is the only country that currently regulates cloning activity. No third country identifies or tracks the offspring or descendants of clones.

Current use of animal cloning and the outlook to 2020

The research suggests that there is currently no commercial cloning of livestock animals in the EU and none is expected before 2020. Commercial cloning of bovine animals is happening in a small number of third countries, particularly in North America and Argentina. Cloning is also being applied to porcine, ovine and caprine animals in third countries, but to a much lesser extent. Commercial cloning is concentrated in the US, Canada and Argentina, although there is some activity in New Zealand, Australia, Chile, China and South Korea.

Commercial cloning of beef and dairy cattle is likely to continue in third countries. It is expected to become more efficient and less expensive, but remain limited to high value breeding animals. Commercial pig cloning may also become more widespread by 2020. Its application to ovine and caprine animals is expected to remain limited.

The most likely route for clones, clone offspring and descendants or their reproductive materials to come into the EU is as reproductive materials from bovine animals, and possibly porcine animals from North America, and beef products from Argentina. Offspring of bovine dairy clones have been produced in the EU from imported reproductive materials from North America (two such animals entered the UK food chain in 2010). It is possible, if unlikely, that equine clones produced for sport could enter the EU food chain when the animals reach the end of their working life or through equine meat imports from third countries.

Supply chain and trade profile

The supply chains that may be affected by the proposed approaches to regulation of animal cloning reach from 'farm to fork', including the breeding sector, producers, markets, slaughterhouses, cutting plants, meat and dairy processors, wholesalers, retailers, as well as importers of live animals, reproductive materials and food products. Species-specific information is available on the number of enterprises involved in animal breeding and production, as well as for imports of live animals and their reproductive materials. Beyond these points in the supply chain the available data only provide aggregate numbers of enterprises across the different sectors.

The policies potentially affected a very large number of businesses – relatively few firms in the breeding sector but very many producers, processors and retailers. There are fewer than 10 companies operating in the EU that could conduct cloning activities (none are known to be doing so). Approximately 300 AI companies operate in the EU livestock breeding sector. There are an estimated 120 importers of reproductive materials. Almost all the importers of live animals deal in equine animals, though there are a few importers of bovine, porcine, ovine and caprine animals.

The EU has nearly 8 million producers of bovine (3.3 mil), porcine (2.7 mil), ovine (1.2 mil) and caprine (0.7 mil) animals. The total number of markets, slaughterhouse and cutting plants is unknown, though there are an estimated 15,000 of these operations for bovine animals. Further down the supply chain there are around 82,000 processors / manufacturers, 83,000 wholesalers, and 624,000 retailers of meat and dairy products. There are around 715 importers of meat and dairy products.

The measures assessed could affect trade, particularly imports into the EU. At present:

■ Parts of the EU livestock sector are heavily reliant on imported reproductive materials, particularly from US and Canada. Commercial cloning activities occur in both countries, but the proportion of materials sourced from clones, their offspring and descendants is unknown.

■ A small number of live bovine, ovine and caprine animals and a larger, but still relatively small number of porcine animals are imported to the EU each year. Due to the high transportation costs, these are all expected to be high value breeding animals, which the EU livestock sector also considers to be important to the breeding industry. A relatively large number of equine animals imported into the EU each year (11,000 in 2011), but these are all expected to be for sport and leisure purposes rather than food production.

■ The EU is a net importer of beef and veal worth around €1.7 billion per year. Sheep meat imports are valued at approximately €1 billion. Cheese and butter are worth more than half a billion euro, despite the EU being a net exporter of these products. 95 per cent of beef imports are sourced from eight countries, with 70 per cent coming from Argentina, Brazil and Uruguay. Milk and dairy products are sourced primarily from Switzerland, New Zealand, and Ukraine and Belarus. The EU is self-sufficient in pig meat though there is small volume of pig offal imports from Switzerland and of pig meat, mainly from US and Chile. Sheep and goat meat is primarily sourced from New Zealand and Australia. Around 70% of equine meat is sourced from Argentina, Brazil, Uruguay and Mexico, most of the remainder is sourced from Canada and the US.

Feasibility and impacts of the four approaches[108]

The individual measures provided are not, with a few exceptions, viable in isolation so for the purposes of analysis were combined into coherent 'packages' of measures. In some cases, different strategies have also been modelled to explore the implications of alternative possible interpretations of the stated policy objectives. For example, for traceability, one strategy looks at the impacts assuming that best use is made of existing traceability systems, another looks at the impacts of implemented full traceability of every individual animal, and another looks at whether the objectives could be achieved via voluntary approaches.

The feasibility and impact assessment process therefore involved, for each approach: specifying the packages of measures; mapping these packages onto the supply chain; defining the obligations that the packages place on different sectors and the systems required to achieve the objectives of the different approaches; assessing the feasibility of each package; analysing the impacts on operators and competent authorities arising from the packages, including impacts on SMEs, EU competitiveness, consumers and the environment. The feasibility and impacts of the four approaches have been considered comparatively and progressively through the supply chain, from packages that focus on live animals and their reproductive materials through to food products.

Feasibility

The feasibility assessment considered the issues involved in the construction and operation of systems that could be developed to deliver on each of the four approaches. It focused on technical feasibility, that is, whether a compliant system could be constructed, as well as the strengths and weaknesses of each package of measures.

Feasibility of packages focused on live animals – clones

The suspension of the cloning technique in the EU and marketing of clones and traceability of live clones by adapting existing traceability systems are both feasible (measure S1 / package S-A, measureT1 / package T-A). Use of the cloning technique requires specialist expertise and technology not widely available. Clones are high-cost animals that would be used for breeding purposes. As such, they are highly identifiable since operators involved in breeding such high-value animals tend to keep detailed records of the animals. With few firms to regulate, domestic cloning would be relatively easy for competent authorities to control. Imports are more problematic, but there are only a small number of animals to control. Imported live animals can be controlled relatively easily through risk-based surveillance of trade focusing on the main sources of food production animals with the highest levels of cloning activity.

Feasibility of packages focused on reproductive materials from clones

Suspension of the marketing of reproductive materials from clones (package S-B) and traceability of reproductive materials from clones (package T-B) under all traceability strategies are feasible without significant adjustment to existing EU (or third country) systems. The production of reproductive materials is already a highly regulated industry in the EU and in the third countries from which the EU sources imported materials. Individual

[108] As defined in Commission Roadmap on measures on animal cloning for food production in the EU http://ec.europa.eu/governance/impact/planned_ia/docs/2013_sanco_007_use_of_cloning_technique_for_food_production_en.pdf

identification and traceability is already enabled in the EU for all semen and embryos. There is no known domestic production of clone reproductive materials for bovine, porcine, ovine or caprine animals. Private sector agreements also already identify cloned reproductive materials from bovine and equine animals originating in the US and Canada. There is no known trade in reproductive materials from clones of the other species.

Feasibility of packages focused on live animals – offspring and descendants

Suspension of the marketing of clone offspring and descendants (packages S-C, S-D), and the traceability of clone offspring and descendants (packages T-C, T-D) using existing infrastructure are both feasible, but would require considerably more adjustment to existing systems than controls that applied only to clones. These packages are more vulnerable to fraud than those covering only clones and clone reproductive materials; third countries are unlikely to change their traceability systems to ensure that imports of live animals into the EU conform to EU requirements. Together, these issues put packages related to clone offspring and descendants at risk of not meeting their objectives.

Domestically produced offspring of clones are identifiable due to agreements with North American operators to identify reproductive materials from clones. The offspring produced from these reproductive materials are most likely to be high-value breeding animals and therefore, records will be kept of these animals' parentage. Identifying domestically produced descendants will be complicated by the record keeping required. As descendants become part of multiplication herds, parentage information may not be fully reliable due to mixing of animals on farm. Incentives may not encourage compliance, especially if operating the system entails additional cost and identification of animals as clone descendants has an impact on their market value.

Few live animals of the species covered here are imported into the EU and those that are imported are 'high value' animals whose heritage would normally be documented. Offspring of clones will be relatively easy to identify since parentage records are kept for these high-value animals for at least the previous generation. Identifying clone descendants is much more complicated than for clone offspring because current systems in third countries do not require traceability of clone offspring or descendants. Assuming that the EU requires documentary evidence at the point of import, this package would therefore require countries exporting to the EU to establish new systems that identify each clone offspring and descendant. These systems would need to incorporate trade in animals and reproductive materials amongst third countries to be comprehensive. It seems unlikely adequate systems would be built.

Information on the pedigree status of reproductive materials would be needed to implement these packages; such documentation is not currently required. Systems in place in North America to identify clone reproductive materials do not extend to reproductive materials from clone offspring or descendants. Additional steps would need to be taken by operators to identify these reproductive materials as derived from clone offspring or descendants.

'Legacy' presence of clone offspring and descendants in the EU is a potential problem and a source of additional regulatory costs for suspension and traceability packages covering descendants because identifying all such animals could be difficult and expensive. A decision would be needed on how to treat these animals. One option would be to accept a low level legacy presence of clone offspring and descendants in the food chain and focus efforts on excluding new sources.

Feasibility of packages that require identification of the status of all animals or batches of animals/reproductive materials

Packages covering traceability of clone offspring (T-C, Strategy 1 – ID all animals or batches and Strategy 2) and descendants (T-D, Strategy 1 - ID all animals or batches and Strategy 2) are technically feasible, but would require major changes to the systems for some species, even where there is likely to be little, if any, cloning activity.

A traceability strategy that requires identification of the 'clone status' of all animals or batches of animals will require adjustment to all existing traceability systems to enable an indication to be provided as to whether or not the animal is a clone, clone offspring or descendant, or batch of animals contains animals that are clones, clone offspring or descendants. At present, this should be straightforward for porcine, ovine and caprine animals, since cloning activity for these species is very limited. Bovine animals are more complicated because offspring and descendants may be produced in the EU. There is also an issue of 'legacy' bovine offspring and descendants in the EU.

Traceability approaches that require individual animal identification and traceability will require significant adjustments to existing traceability systems and may require new systems where existing systems cannot cope with identifying the number of new animals that require traceability. Third countries are unlikely to implement new traceability systems in the absence of evidence on human health or safety risks.

Feasibility of packages focused on food products

The greatest challenge to feasibility of packages covering food products arises from imports. Confirmation of the status of these food products as being derived from clones, clone offspring or clone descendants would need to rely on traditional documentary methods used in supply chain traceability systems. This kind of documentation is not currently required for imported food products. International trade in reproductive materials will make it difficult to be certain that the animals, and thus food products, from a country that does not use the cloning technique were not actually derived from reproductive materials from clones, their offspring or descendants obtained in another country. Extension of traceability requirements into processed food products would not be feasible in most instances.

Suspending the marketing of food products derived from clones (S-E) is the most feasible of the packages covering food. The number of potential EU suppliers is small. Proportionate systems for suspension of clone imports are also technically feasible through working with trading partners. The risk of clones being used systematically for food in the next few years is low as clones are uncommon and very valuable, though there is a theoretical risk of such animals entering the food chain at the end of their working lives as breeding animals. Nonetheless, demonstrating and documenting that foods are free of clones would require systems that do not currently exist. Third countries that export to the EU would require appropriate traceability systems or segregated supply chains, unless a pragmatic agreement was reached with third countries to exclude clones from exports to the EU. Verification of claims would not be possible. Moreover enforcing the suspension of use of clones in imported food products would be a significant challenge due to the high volume of EU meat product imports, especially bovine products.

Constructing a system that can exclude clone offspring (S-F) and descendants (S-G) is less feasible than one covering clones alone. Trading partners would need to either identify and

trace all clone offspring as live animals and then trace them through the food chain to demonstrate that exports to the EU did not contain products derived from clone offspring, or to establish fully segregated 'clone-free' supply chains. The feasibility of the system for all animals would depend on the specification of the evidential requirements applied by the EU to imports under the new EU 'cloning' legislation.

Traceability packages for clone offspring and clones descendants (T-F, T-G) face the same challenges as suspension packages for food products derived from clone offspring and clone descendants – identification and traceability beyond clones themselves is difficult, if not impossible, without completely segregated supply chains. The EU's trading partners (and those countries' other trading partners) will need to adapt their traceability systems. It seems unlikely they will do so.

Feasibility of labelling and premarket approvals for food products derived from clones, their offspring and descendants

Labelling and premarket approval approaches for food products derived from clones (package L-A, P-A), their offspring (package L-B, P-B) and descendants (package L-C, P-C) are feasible only to the extent to which the underlying traceability systems are feasible. The limitations of traceability described above are thus also present for labelling and premarket approvals. Where it is difficult or impossible to confirm that a food product contains clones, their offspring or descendants (e.g. mixed meat products), then it will be difficult to label these products, for example, and there are likely to be more errors in identification.

A labelling approach that requires 'positive' labelling (e.g. "contains products derived from descendants of clones") is likely to prompt the industry to exclude products from the supply chain that would be required to carry the positive label. This is due to the negative perception of the cloning technique by consumers and supply chain operators' concern about negative responses of consumers to any label referring to cloning. A labelling approach that required food products to be labelled with information telling the consumer that they may be derived from clone offspring or descendants could be used in a context where food exports to the EU were unable to provide full traceability. This would enable imports to continue in a way that would not be possible if declaration of clone status was a formal requirement for import into the EU.

A labelling approach that is voluntary and 'negative' (e.g. "produced without cloning technology") is likely to be appealing to some operators. A certification approach could be used in which sufficient documentary evidence would confirm that the process used involved sufficient effort by the supply chain to exclude these animals, even if the product is not verifiable. Even so, there is a risk that the two labelling packages covering food products from clone offspring (L-B) and descendants (L-C) would not achieve their objectives because of difficulties in confirming the claims made for imported food products derived from offspring and descendants.

Impacts

Given that little or no commercial cloning is expected in the EU in the period to 2020, virtually all of the impacts arising from the proposed approaches assessed in this study arise from the development of systems to control activities and products that are not present in the supply chain or, in the case of bovine animals, present only at very low levels. Direct and indirect effects are expected on the EU supply chain. The imposition of new requirements that

exporters in third countries may be unwilling or unable to satisfy poses a risk of causing interruption to trade, especially for packages that cover clone offspring and descendants, and food products. These trade-mediated effects could negatively impact the EU's animal breeding at one end of the supply chain, and affect choice and price of food for consumers at the other. Some packages are also expected to cause a large number of businesses to spend time (and thus incur cost) understanding the implications of the new legislation for their operations, even in circumstances where they would not be expected to encounter any animals or products regulated (under that legislation). This is a form of additional deadweight cost.

By making products derived from clones, clone offspring and clone descendants more 'visible', the interventions are likely to reinforce a drive towards exclusions of such animals and products from the supply chain. Labelling requirements, which makes clone status visible to consumers, are likely to further reduce demand for livestock animals produced from the use of cloning technology and their introduction into the EU supply chain. Mandatory 'positive' labelling is likely to result in downward pressure on upstream operators by retailers and manufacturers to exclude clones, their offspring and descendants from the supply chain. Operators will face additional costs to take measure to exclude these animals.

Fully segregated supply chains are feasible in some cases, such as for milk, but due to the lack of market demand for products formally recognised as being derived from clones (or clone offspring / descendants), operators are unlikely to invest in those operations.

Direct burdens

The direct burdens on EU operators will vary significantly depending on the approach taken, the information requirements of the approach and the compliance, reporting and enforcement strategy of competent authorities (sections 7.4 and 8.4).

'Learning costs'

'Learning costs' are the staff time and advisory costs incurred by directly affected operators as they familiarise themselves with the new legal requirements (sections 7.4.2 and 8.4.2). Under the suspension and traceability (Strategy 1) approaches such costs are likely to be modest where packages focus on breeders and the 'upstream' parts of the supply chain operators (estimated at less than a €100,000 for packages S-A and T-A due to the small number of directly affected operators, and approximately €1 million for packages S-B to S-D and T-B to T-D). Most of the costs under these packages are borne by the AI industry.

Learning costs increase significantly where packages include regulation of food products. Under the suspension packages (S-F to S-G) meat food importers will also be directly affected, increasing costs by more than €5 million. Under traceability packages (T-E to T-G) costs could increase by approximately €200 million under each package as other 'downstream' operators in the EU supply chain (slaughterhouses, markets, food importers, processors, manufacturers, wholesalers, and retailers) are required to learn about the new requirements (Table 7.5 and Table 8.9).

Learning costs for breeders / holdings can vary from relatively modest (a couple of million euro) where packages focus only on identification and traceability of clones themselves to hundreds of millions of euro where all holdings must learn about new requirements related to traceability under Strategy 1 if all animals/batches of animals must be identified as a clone (or not) and under Strategy 2 if all individual animals must be identified and traced. This is because the scope of the regulation changes from focusing only on those operators handling

animals that may be clones, offspring or descendants to all operators raising livestock animals in the EU. Even if each of these operators only needs a minimal amount of time to learn about the new requirements, there are nearly eight million operators that may be directly affected under these scenarios.

Reporting and inspection costs

Reporting and inspection costs are incurred as breeders, livestock producers and food business operators responses to requests for information (i.e. reporting) and/or inspections from competent authorities (CAs) (sections 7.4.2 and 8.4.3).

CAs' approach to regulation will determine the precise burdens on operators. If CAs take a risk-based approach that focuses on EU organisations capable of conducting cloning and targeted checks on imports, then regulatory costs can be reduced. If CAs implement a comprehensive monitoring and reporting framework then the costs will be far higher. In all cases, the costs increase as the packages involve more of the supply chain, and particularly for those that cover food products.

Annual reporting burdens under the suspension approach and (the less ambitious, Strategy 1) traceability approach will be modest where packages focus on clones. For example, traceability costs are estimated at approximately €2,000 per year for packages focusing on clones (T-A and T-E). Estimated annual reporting burdens grow to approximately €32,000 under traceability packages that cover clone offspring and clone descendants (packages T-B, T-C, T-D, T-F, T-G) (Table 7.7 and Table 8.13). Additional annual reporting burdens could be zero to negligible for breeders/holdings under traceability Strategy 1 where positive ID is required only for clones, their offspring and descendants (sub-strategy (a)) but more than €100 million per year if all animals require individual identification where this is not already a requirement under EU legislation (Strategy 2) (Table 8.15).

Compliance costs

The traceability approach will impose additional costs on competent authorities and businesses, including livestock producers. The costs to CAs include one-off costs for changing paper-based documentary and IT based traceability systems to achieve compliance with the new rules and on-going costs for operation of the expanded system (section 8.4.4).

If the traceability approach focused on making best use of existing traceability infrastructure (Strategy 1) consultations with selected MS representatives suggest that these changes could be made through minor adjustments to existing systems. Sub-strategy (a) requires identification only of clones, their offspring, descendants, reproductive materials and derived food products, which would also keep costs low given the small number of animals in the system. Sub-strategy (b) would impose much higher costs since it would require an indication of the status of all animals or batches of animals, and derived products (i.e. clone, offspring, descendant 'yes' or 'no').

If each animal had to be individually identified for all species without derogations (Strategy 2) much larger investments in databases and associated systems would be required. Countries with large populations of porcine, ovine and caprine animals would need to have systems that could accommodate individual ID of all of these animals (potentially millions of additional animals and many millions of animal movements). New systems are likely to be needed to record this information. The costs of adjusting or creating new systems under Strategy 2 would likely run into millions of euros in total across the EU.

There would also be large additional capital and operating expenses for the livestock sector to work to the new system in which individual animal ID and traceability is required. That change would involve removing the derogations put in place under current traceability legislation. There would be additional costs in acquiring and maintaining equipment (such as ear tags, and modifying readers). The requirement to identify the clone status of each small ruminant would require more than 50 million animals to be tagged each year at a cost to breeders and producers in tags and other equipment estimated at €37million to €98 million/year. The cost for porcine animals would be higher because many more porcine animals are produced each year (approximately 260 million) than ovine/caprine animals (approximately 89 million), and most are currently batch-identified. The cost is estimated at between €193 and €510 million each year (section 8.4.4.3). Added to this would be the cost of time taken by operators to administer the system. The inputs required for an accurate estimation of additional costs are not all available but the incremental cost of recording clone status on an individual animal basis is estimated at €24 million for ovine and caprine animals and €71m/year for porcine animals (Table 8.20).

The suspension approach would not impose additional compliance costs on the EU. But it would require compliance expenditure by third countries that would be required to develop segregated supply chains or traceability systems sufficient to demonstrate that their exports to the EU of animals were not clones, their offspring or descendants, and exports of reproductive materials and food products were not derived from such animals, much as would be needed under the traceability approach (section 7.4.1). These systems do not exist at present.
The labelling and premarket approval approaches would impose further compliance costs on operators and competent authorities. These include:

■ Costs for labelling changes: operators that need to adapt or redesign product labels in order to accommodate new labelling requirements will incur additional costs that are expected to range from as little as €100 to as much as €13,000 per stock keeping unit depending on the requirements (Table 9.3). The incremental costs will be lower where changes can be integrated into the labelling 'lifecycle' and included during the regular 'refresh' of a product label.

■ Costs for premarket approval: the expected costs to industry of approvals are less than €30,000 per product for a purely administrative approval mechanism. Toxicological tests are unlikely to be required, but if they were, the costs could be more than €300,000 for testing and detailed risk assessment (section 10.4.2). The designated authority will also incur costs to establish the approval system. The assumptions made about evidence required are illustrative for this appraisal only.

The total expected costs on the supply chain are small because it is expected that relatively few products would be labelled or brought to the market. The detail of the labelling requirements (e.g. whether they specify a note in the list of ingredients or a prominent front of pack label) would influence impacts.

In a scenario where imported foods were required to be labelled as potentially derived from clones, clone offspring or clone descendants (i.e. "may contain"), there would be impacts on exporters in third countries. This route would however enable food imports to continue in circumstances where third countries are unable (or unwilling) to establish robust traceability systems for such animals and derived products.

Trade-mediated effects

Many of the measures assessed risk disrupting EU import trades, with the potential for impacts across the supply chain, from the artificial insemination and elite breeding sectors all the way through to consumers. Imports of reproductive materials are of direct importance to the EU breeding and livestock production sector and benefit the rest of the supply chain indirectly. If the EU imposes conditions relating to clone status that exporters are unable or unwilling to satisfy, €3.67 billion worth of annual imports of meat and other animal-derived food products are at risk of interruption (sections 7.5.3 and 8.5.2). Given the international trade in reproductive materials, animals and food, to achieve traceability or exclusion of products of clone offspring and descendants from the EU supply chain would demand that the other trading partners of the EU's direct trading partners have adequate traceability systems for clone status – in effect a global traceability system. The feasibility and reliability of such a system is in doubt.

The size of such trade-mediated contingent risks varies depending on the scope of the legislation. The precise impacts will also depend on the behavioural responses by the EU supply chain and by actors in third countries. The analysis has therefore estimated trade and jobs 'at risk' rather than specifying definitive losses. The value of trades and the number of businesses at risk are set out in Table E.1. Both short-run effects (e.g. loss of access to South American beef) and long-run effects (e.g. impacts on EU dairy breeding strategies and productivity if EU breeders are denied access to elite genetic materials from North America) are anticipated.

EU requirements to trace or excludes products based on a clone status add cost and complexity for operators exporting to the EU and for EU importers. Evidential requirements under all scenarios are expected to be harder to meet, and therefore entail additional costs.

Premarket approvals (PMAs) could also create issues for importers of meat and other products into the EU if importers cannot be sure that imported products are free of animal clones, offspring and descendants because they will not be able to place them on the EU market. PMA requirements risk triggering trade disruptions to meat and other animal product imports. Generic authorisations could reduce the problem. Even under a generic system, issue remains until the first authorisation is granted Authorities could provide for a transitional period for PMA to allow food products that may be derived from clone offspring and descendants to continue to enter the market without approval until end of the transition period. A PMA requirement would create an additional barrier for exporters to the EU over and above that posed by traceability requirements.

Impacts on competitiveness

In addition to direct economic impacts and indirect trade-related effects on EU and third country operators and competent authorities, there may be impacts arising from the proposed approaches related to competitiveness, including cost competitiveness, capacity to innovate and international competitiveness. These are each considered in turn below.

Table 1: Summary of potential trade-mediated impacts arising from suspension and traceability approaches

Issue	Package	Number of businesses at risk	Value of trade at risk (€m/yr)	Significance of impacts if full cessation of trade
Cloning technique is unavailable in EU	All suspension packages (S-A to S-G)	**LOW** – no known food-related companies conducting cloning in the EU	**N/A**	**LOW** – potential limited impact to 2020 in the dairy sector
Imports of live animals cease	All suspension and traceability packages (S-A to S-G and T-A to T-G)	**LOW** - small numbers of live animals imported	**LOW - 2.3**	**MEDIUM** – small numbers of animals, but important to EU breeding sector
Imports of reproductive materials cease	S-B to S-G and T-B to T-G	**MEDIUM** – 120 companies may go out of business; 294 AI companies may be affected	**MEDIUM - 14**	**MEDIUM - HIGH** The EU breeding industry is heavily reliant on imported reproductive materials, especially for bovine animals
Imports of food products cease	S-F, S-G and T-F, T-G[109]	**MEDIUM –** 715 companies may go out of business; effects greatest for bovine, ovine and equine meat importers	**HIGH - 3,667**	**LOW –** caprine food imports **MEDIUM –** porcine, ovine and equine food imports **HIGH –** bovine food imports

Cost competitiveness

Packages that extend beyond control of cloning are expected to have negative impacts on the cost competitiveness of EU businesses. It is not clear that EU controls on use of cloning would confer an advantage in export markets that would help to offset the additional costs. In the EU domestic market the negative impacts of the additional administrative burdens would be mitigated by an increase in demand for domestically production if access to imports was reduced.

The largest direct cost impact domestic producers is triggered by a requirement for individual animal traceability in the porcine and ovine/caprine sectors; many producers in those sectors already exist on low margins and it is unlikely that the incremental costs could be passed in full down the supply chain. The packages that impose additional traceability and reporting burdens would make these sectors less competitive. Indirect effects may be greater than the direct effects, particularly where trade losses occur due to third countries not being able or willing to meet traceability requirements. If trades are halted, input costs could rise in the EU, for example, in the breeding sector.

[109] Food products derived from clones are highly unlikely since clones are scarce and expensive and, it is assumed, could be excluded through pragmatic measures without putting EU trade as a whole at risk.

Packages	Direct effects	Indirect effects
Control of cloning and use of clone reproductive materials S-A, S-B & T-A, T-B	None as no commercial cloning expected in the EU in the baseline (business as usual) scenario	Some additional administrative costs to meet requirements Risk of loss of access to imports of live animals and RM which could raise input costs, if existing private schemes are not recognised and extended
Controls on clone offspring and descendants S-C, S-D & T-C, T-D	Negative impacts on farmers and importers of animal genetics for bovine species Where all animals require ID, significant additional administration and equipment costs in porcine and ovine/caprine sector would negatively impact cost competitiveness of these sectors	Potential trade losses where third countries do not meet traceability requirements to allow importers to meet requirements of suspension or traceability approach in the EU –could raise input costs in the EU
Controls on food S-F, S-G & T-F, T-G	Increased compliance and reporting costs	Risk of widely distributed negative impacts due to loss of imports Some negative impacts may be offset if imports are restricted from third countries due to lack of compliance with traceability requirements and EU producers benefit from loss of competition

Impacts on EU's capacity to innovate

The indirect (and uncertain) trade-mediated effects have the potential to immediately impact on innovation and thus productivity growth in the livestock sector in the EU, particularly for bovines. If trading partners cut off trade with the EU in live animals and reproductive materials, it would also affect Europe's access to high quality genetics in key breeds and thus the sector's ability to improve the quality of the EU breeding stock. Suspension measures which prohibit use of cloning technologies risk inhibiting the EU's capacity to innovate in this area, though the short-term impacts of the approach on cloning research and innovation are expected to be small.

International competitiveness

Traceability and suspension packages that reach beyond regulation of clones and clone reproductive materials risk having a negative impact on the EU's international competitiveness. Packages that result in lack of access to high quality genetic materials from third countries could, especially over the longer term, negatively impact on competitiveness in price-sensitive export markets. The additional administrative burden imposed on the food chain would be expected to reduce the competitiveness of the affected sectors. This is particularly true of the more ambitious traceability strategy which could have negative impacts for porcine, ovine, caprine and equine animal industries due to significantly higher costs imposed on operators.

There would potentially be some benefits for EU domestic producers in-so-far as:

- Packages that interrupt imports could reduce domestic producers' exposure to competition in the EU market, which could improve their competiveness in the domestic EU market;
- Suspension, traceability, and labelling approaches that enable 'clone free' status for EU products, could have a positive impact on demand for those products in third countries if this is seen as a premium attribute by consumers; and
- Competitiveness impacts arising from the labelling and premarket approval approaches are expected to flow predominantly from the traceability systems underlying them.

Impacts on SMEs

The four approaches as specified do not provide an exclusion from the requirements for SME businesses. The food chain contains large numbers of SMEs, from the farming sector through to manufacturing and retail. All four approaches therefore have the potential to impact on SME growth. The impacts on SMEs are likely to vary depending on the approach and strategy chosen, as well as information requirements. Indicative likely impacts are described in Table E.3.

Package	Sectors	Principal impacts expected	Comments	Significance
Control of cloning S-A & T-A	Live animal importers	Risk of loss of market in live animal imports	Aggregate value of trade is small Few businesses rely on trade in live animals to the EU, but important to those few businesses Animals are high-value and therefore likely to be traceable with modest effort	High for affected businesses Low overall
Clones plus clone reproductive materials S-B	Importers of RM	Materials will need to be identified as derived from clones and excluded (S-B) from EU market	Existing system can and does already screen out clone RM where required	Low
Clones plus clone reproductive materials T-B	Importers of RM	Materials will need to be identified as derived from clones and traced in EU market	Materials are already traceable and identifiable in major exporting countries as derived from a clone	Low
As above plus offspring and descendants S-C, S-D & T-C, T-D	Importers of RM	Risk of loss of access to imported RM leads to loss of business for importers where exporters cannot or will not identify RM from clone offspring/ descendants	Existing 'screening' system does not extend to offspring and descendants of clones	High
	Breeders	Loss of access to high quality Holstein/other genetics would negatively affect breeding programmes	Some Member States are heavily dependent on AI and imported RM for breeding programmes	High in select MS Low in other MS
As above, plus food S-E, S-F, S-G & T-E, T-F, T-G	Food importers, processors, manufacturers, retailers etc.	Risk of loss of access to imported meat and dairy suppliers Import substitution from domestic supply should raise prices/profitability for EU suppliers	Higher input prices likely Some businesses rely entirely on imports Food products derived from clones (T-E) are highly unlikely and could be excluded through pragmatic measures without the negative impacts expected from T-F and T-G.	High/critical for businesses dependent on imports General negative impact from higher input prices

Social (employment) impacts

Few EU jobs are currently sustained by commercial livestock cloning so suspension will have little direct impact on employment in the breeding sector. The more substantial employment impacts expected are:

- Employment losses prompted by the additional administrative burdens place on livestock producers and other food business operators (FBOs); and
- The risk to jobs in EU livestock sector and supply chains created by requiring third countries to comply with traceability conditions that they may be unable or unwilling to meet.

Direct and indirect (trade-mediated) employment impacts of the suspension and traceability approaches, as well as labelling and premarket approvals are summarised in Table E.4.

Impacts on consumers

The suspension and traceability approaches that reach beyond control of cloning and clone reproductive materials could result in negative impacts on EU consumers. These may include both price effects (i.e. price changes in consumer markets) and choice effects (i.e. changes in the availability of goods and services available to consumers). Short run impacts are likely to be highest for packages that include food products, mainly because of the potential trade-related impacts on food imports. These could limit the availability of certain products and increase prices where alternatives must be sourced from other trading partners or supplemented by domestic production. Traceability Strategy 2 may also increase the production costs for operators, and these costs may be passed to consumers, increasing costs to purchase these products.

	Direct impacts	**Indirect (trade-mediated impacts)**
Suspension	Negligible for all packages – few if any EU jobs sustained by commercial cloning in the food chain	Potential high negative impacts; suspension puts jobs at risk in businesses importing products and in downstream supply chains – impacts expected in the EU and third countries, especially for packages related to food products (S-E, S-F, S-G)
Traceability – Strategy 1	Negligible for live clones (T-A) and their reproductive materials (T-B) – few EU jobs sustained by commercial cloning; reproductive materials are already traceable and the status of the RM is easy to determine	May have negative impacts for domestic and third country operators for reproductive materials from clone offspring (T-C) and descendants (T-D) – third countries unlikely to implement required systems to enable traceability. Packages related to food products (T-E to T-G) could produce significant employment impacts in sectors currently sustaining thousands of jobs in the EU and third countries if traceability requirements results in a cut-off in trade of these products
Traceability – Strategy 2	Direct impacts for live bovine animals, and RM of all species (T-A, T-B) expected to be the same as under Strategy 1 EU jobs would be created for live porcine, ovine, caprine and equine animals to produce tags, equipment, computer systems for individual ID and to implement the systems (T-A, T-C, T-D)	Impacts for food products of all species (T-E to T-G) expected to be the same as under Strategy 1. Employment gains through expanded traceability for porcine, ovine, caprine and equine animals likely to be offset by employment losses caused by additional administrative burdens place on livestock

		sectors and supply chain.
Labelling	Few products likely to be brought to market under 'positive' labelling Voluntary labelling may result in creation of a small number of jobs in administration of requirements, inspections, etc.	Impacts are expected to be related to the underlying traceability systems, rather than labelling itself
Premarket approval	No measurable employment impacts expected – demand for approvals likely to be zero	Primary impacts are expected to be related to traceability rather than the PMA itself; though PMA would present an additional barrier to trade if / once the traceability issues had been overcome.

Package	**Price effects**	**Choice effects**
S-A, S-B & T-A, T-B (Strategy 1, positive ID only)	None expected	None expected
S-C, S-D & T-C, T-D (Strategy 1, positive ID only)	Price effects in dairy markets if dairy sector loses access to imported reproductive materials Marked short run effects may occur in MS with high dependence on imported RM and heavy use of AI Price effects in meat and meat products sector if meat production sector loses access to imported RM	Limited, except as a consequence of product scarcity
T-A, T-C, T-D (Strategy 1 and 2, ID all animals/batches)	Negative price effects if all animals must be identified	None expected
S-F, S-G and T-F, T-G (Strategy 1 and 2)	Price effects in dairy markets if imports of dairy products cease Potentially significant price effects in meat and meat products sector if imported meat products cease (primarily bovine, as well as ovine meats)	Product-specific and seasonal due to loss of access to specific brands/types of dairy product. Significant for bovine meat and meat products Significant for ovine and caprine meat products Limited for porcine and equine meat products

Environmental impacts

The evidence suggests that the negative welfare impacts are concentrated in the cloning process itself. The incremental animal welfare benefits are thus highest for the measures and packages that focus only on cloning (measure S1, package S-A; measure T1, package T-A). As the scope of the packages increases to cover offspring, descendants and food, the

additional animal welfare benefits decline while the additional economic impacts, and risks, increase.

There is uncertainty about the impacts of use of cloning on genetic diversity in domesticated species, but the most likely outcome is a reduction in the genetic diversity of the gene pool, and potentially further concentration in the use of a small number of breeds. The EU's exposure to these impacts is likely to be indirect, mediated through the use of genetic materials imported from North America. Regulating the use of cloning could reduce the risk of this loss of diversity, though it could also deny EU breeders access to high quality genetics from North America that are used to supplement 'domestic' genetics. If, *in extremis*, imports of reproductive materials ceased then EU breeders in the dairy sector and elsewhere would be denied access to the global 'pool' of genetic resources used in animal breeding and would need to develop alternative strategies for the same breeds or turn to other domestic EU breeds.

Conclusion

The analysis suggests that controls that were limited to the use of cloning in the EU in the period to 2020 would not have a significant economic impact, partly because little or no commercial cloning is expected even without regulation. Suspension of, or requiring traceability for, clone reproductive materials is feasible and would not have a large economic impact if existing supply chain arrangements can be recognised, formalised and extended. However, as the scope of the packages increases beyond cloning to cover offspring, descendants and food, the incremental animal welfare benefits decline while the additional economic impacts, and risks, increase. Packages also become progressively less feasible. The key issues are:

- The costs associated with traceability requirements imposed on the EU supply chain under the traceability approach, and the exact specification of those traceability requirements;
- The systems or documentary evidence that entities exporting animals, reproductive materials and to the EU will be required to have to support declarations on whether those goods are clones, clone offspring and clone descendants, or derived from such animals; and
- How to foster a system that is robust and reliable in a context where claims of the clone status of animals and products will not (with few exceptions) be verifiable except by documentary evidence, where mistakes as to parentage are easily made (e.g. through mixing of young animals and parents in extensive systems), and where incentives in the supply chain may not encourage compliance (e.g. higher costs, lower market value).

The proportionality of the actions represented by many of the packages evaluated is doubtful given the absence of commercial cloning in the EU and that commercial cloning for food production in third countries is largely confined to bovine animals.

ANNEX VI: SUMMARY OF EU REQUIREMENTS ON THE IDENTIFICATION AND TRACEABILITY OF LIFE ANIMALS AND REPRODUCTIVE MATERIAL AND NOVEL FOOD

1. Live animals

a) For Bovine animals, the main objectives of the current system of identification, registration and traceability are to identify individually and to trace animals for the control of infectious diseases and to re-establish consumer confidence in beef and beef products through transparency and traceability of bovine animals and the meat derived.

The system is based on **4 elements**: "double ear tag", "holding register", "cattle passport" and "national computerised database". The identification is individual and the registration of individual movements is compulsory by keepers in the holding register and in the database. The holding register and the database contain among others information on the date of birth and the mother of each bovine animal.

In the case of imported live bovines, EU legislation ensures identification on the animal in question upon arrival and subsequent tracing once the bovine enters the EU. Information about parentage and date of birth is not requested in the import health certificate. However the whole pedigree (parents and grand parents) is provided in the zootechnical certificate for pure bred animals which are intered to be registered in herd books. The total number of live bovine imported into the EU is limited but these are mainly pure bred animals with zootechnical certificates.

b) For sheep and goats, the objective is mainly animal health. Sheep and goats born after 1 January 2010 must either be i) individually identified with an electronic identifier and an eartag or ii) by two conventional eartags. National computerized databases have been set up also for ovine and caprine but only holdings have to be registered. The registration of individual animals and their movements has only to be done in the holding registers and not in the database. The holding register and the database do not contain information on the parentage

It has to be noted that the current legislation on small ruminant identification provides for a derogation to individual identification for slaughter animals under 12 months old under certain conditions.

In relation to imports of sheep and goats from third countries, the current import health certificate does not impose to record information on the parentage, but the whole pedigree (parents and grand parents) is provided in the zootechnical certificate for pure bred animals. The number of live sheep imported into the EU is limited.

c) For Pigs, the objective is mainly animal health. The current system for identification in the EU is less sophisticated than the system set up for bovine, ovine, caprine and equine since it is not based on individual identification but on "batch/holding" identification which enables to determine the last holding from which they come from and the holding on which they were born. Each animal is identified at birth with the identification number which is attributed to the farm of birth and keeps it up to slaughtering. The same animals receive a second eartag from the farm of fattening (same number attributed to the whole batch of production). All farms are registered in the national database of porcine holdings.

The database does not contain records of animal movements but all holdings have to register in their holding registers the information related to animal movements between holdings (including slaughterhouses) based on batches of animals. The traceability of batches of animals is therefore paper based (holdings registers and possible documents accompanying the movements of animals).

In relation to imports of pigs from third countries, the current import health certificate does not impose information on the parentage but the whole pedigree (parents and grand parents) is provided in the zootechnical certificate for pure bred animals. The number of live pigs imported into the EU is limited (around 800 per year).

d) For Equine animals, the objective is mainly animal health. Horses born after 1 January 2009 must be individually identified (electronically) but the registration of individual movements is not done in the database. The current system for identification is based on a single lifetime identification document (individual passport) and the registration of individual animals in a database. The database is updated only following to a change in the ownership of the animal. The microchip contains the Unique Equine Life Number (UELN), and the microchip number can be linked to a central database and/or to the passport.

In relation to imports of horses from third countries, the current import health certificate does not impose information on the parentage but the whole pedigree (parents and grand parents) is provided in the zootechnical certificate for pure bred animals. The number of horses imported is around 10000 horses per year, but most of them are not intended for the food chain.

For all species, the responsibility to register and to feed the system with information related to animal movements, births, deaths, etc. falls on the keeper of the animal. EU legislation describes clearly the information to be recorded per every animal, which varies depending on the animal species. This includes information on the mother but only for bovines. Information on the father is not requested for any of the farm animal species.

Table 1: Main EU legislation and type of identification and traceability by species

Species **EU Legislation**	**Identification**	**Traceability (Registration of animals)**
Bovine Regulation 1760/2000	**Individual (Ear tag)**	**Individual + passport** **National Database**
Ovine/caprine Regulation 21/2004	**Individual (EID or ear tag)**	**Individual / holding register** **Batch (Lambs) (Holding register)**
Porcine Directive 2008/71	**Batch (Ear tag)**	**Batch** **holding register**
Equine Regulation 504/2008	**Individual (EID)**	**Individual + passport** **National Database or passport**

2. Reproductive material

Health certificates are required for intra-community trade and imports of reproductive material. Current rules on trade of either EU produced or imported semen and embryo establish a registration system which is based on the individual identification of the donor (semen) or both donors (for embryo). That system ensures that these reproductive materials can only be marketed if the individual identification of the donor animal(s) is indicated on the straws, ampoules or other packaging, containing the individual dose of semen or embryos and on the veterinary import certificate accompanying these products. This information then allows the traceability of these reproductive materials from the breeding centre of production up to the farm of destination.

a) Intra-community trade

- Information in the health certificate contains provisions related to identification and registration of the donor animal(s). For each consignment of semen: approval number(s) of semen centre(s), identity of the donor animal(s), identification mark(s) of doses and the consignee(s). Similar rules for embryo.

- This information is transferred electronically via TRACES.

- Traceability requirements provides for an unique identification number of donor animal(s) which is labelled (bar code) for each semen straw / embryo ensuring full traceability from the donor animal to the farm(s) of destination.

b) Imports from third countries

- Equivalent requirements on identification and registration apply for imports of reproductive material from third countries than to those for intra-EU trade

- Only EU agreed collect and storage semen centres can provide semen to the EU market.

c) National trade

- No health certificate and therefore no registration are needed for national trade of reproductive materials.

- However EU Law foresees that semen centres have the obligation to register the consignee (approved entities of destination) for each semen consignment they put on the market.

3. Registration of zootechnical certificates for trade of live animals and reproductive material (pure bred only).

As regards farmers willing to register their pure bred animals in herd books: on top of the above-mentioned requirements on identification and registration, pure bred animals must comply with additional requirements resulting of the provisions contained in the EU zootechnical legislation. This includes the possibility to have additional information on the parentage of these animals via the herd-books, like registration of both parents and the 4 grand-parents. This information is managed by private organisations and on a voluntary basis. The number of farm animals for which this additional information on identification and

registration could be available represents a small percentage of the total animal farm population in the EU.

a) Imports from third countries

Imports of reproductive material and pure breed animals from third country may on the top of the identification and registration requirements referred in points 1 and 2, comply with additional requirements resulting of the provisions contained in the zootechnical legislation. EU zootechnical certificates[110] are not systematic for the imports of pure bred live animals and their reproductive material as it depends if the farmer of destination intends to register the animal(s) imported or obtained in the national herd-book of the breed.

b) Intra-community trade

- Member States may also impose EU genealogic/zootechnical certificates[111] (delivered by herd-books) for pure breed animals and pure breed reproductive material intended for intra-community trade.

- These certificates provide information on the pedigree (see paragraph 1 b) for registration in the national herd-book of the breed of i) pure bred live animals and ii) the offspring obtained from their reproductive materials.

4. Traceability of food

Food traceability is the ability to track any food, food producing animal or substance that may be destined for human consumption through all stages of production, processing and distribution of foods. For the proper application and enforcement of origin labelling, an effective traceability system is required to ensure the passing of the origin information along the food chain.

a) General EU traceability requirements.

The EU traceability legislation aims at ensuring food safety. Accordingly, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[112] sets out a comprehensive system of traceability within food and feed businesses to meet this objective. The traceability requirements can be summarised as follows:[113]

- ❖ The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed should be established at all stages of production, processing and distribution.
- ❖ FBOs must be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be,

[110] Council Directive 94/28/EC laying down zootechnical and genealogic conditions applicable to imports from third countries of semen, ova and embryo.
[111] Could be replaced by genealogic documents issues by semen centres.
[112] OJ L 31, 1.2.2002, p. 1.
[113] Article 18 of Regulation (EC) No 178/2002; Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law - Conclusions of the Standing Committee on the Food Chain and Animal Health, January 2010, to be found at: http://ec.europa.eu/food/food/foodlaw/guidance/docs/guidance_rev_8_en.pdf.

incorporated into a food or feed. To this end, FBOs must have in place systems and procedures that allow for this information to be made available to the competent authorities on demand.

- ❖ FBOs must have in place systems and procedures to identify the other businesses to which their products have been supplied. This information must be made available to the competent authorities on demand.
- ❖ Food or feed which is placed on the market or is likely to be placed on the market in the Union must be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

The requirement to identify suppliers and other businesses to which products are supplied is known as the *'one step back - one step forward'* approach. The *'one step back - one step forward'* approach implies for food business operators that:

- They must have in place a system enabling them to identify the immediate supplier(s) and immediate customer(s) of their products;
- a link 'supplier-product' must be established (which products supplied from which suppliers);
- a link 'customer-product' must be established (which products supplied to which customers). Nevertheless, food business operators do not have to identify the immediate customers when they are final consumers.

As such, the existing traceability requirements do not foresee a cumulative traceability system.

The traceability requirements set out in Regulation (EC) No 178/2002 are worded in terms of their goal and intended result, rather than in terms of prescribing how that result is to be achieved. This allows certain flexibility to the FBOs in the implementation of these requirements.

b) Traceability of food of animal origin.

As far as foods of animal origin are concerned, Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin[114] sets out additional traceability requirements. In particular, it applies to unprocessed and processed foods of animal origin.[115] It requires FBOs to ensure that the following information concerning consignments of food of animal origin is made available to the FBO to whom the food is supplied and, upon request, to the competent authority:

- an accurate description of the food;
- the volume or quantity of the food;
- the name and address of the food business operator from which the food has been dispatched;

[114] OJ L 242, 20.9.2011, p. 2.

[115] However, it does not apply to foods containing both products of plant origin and processed products of animal origin.

- the name and address of the consignor (owner) if different from the food business operator from which the food has been dispatched;
- the name and address of the food business operator to whom the food is dispatched;
- the name and address of the consignee (owner), if different from the food business operator to whom the food is dispatched;
- a reference identifying the lot, batch or consignment, as appropriate; and
- the date of dispatch.

These information requirements must be updated on a daily basis and kept at least available until it can be reasonably assumed that the food concerned has been consumed.

In addition, Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[116] requires that products of animal origin should have an identification mark indicating the last approved establishment in which the product was handled. The identification mark must indicate the country where the establishment is located and its approval number. Establishments located within the Union must be indicated as EC (or equivalent abbreviation in other languages).

Imports of live animals and animal products from third countries into the EU are governed by detailed legislation in the veterinary field. Third countries exporting to the EU must have traceability systems in place for exports, which are able to provide equivalent standards to those in the EU. In that respect, Regulation (EC) No 853/2004 sets out general obligations for the importation of products of animal origin from third countries, including the fact that foods of animal origin can only be imported from countries and establishments laid down in EU lists.

c) Specific requirements for fresh beef

With regard to bovine animals and fresh beef, Regulation (EC) No 1760/2000[117] and Commission Regulation (EC) No 1825/2000[118] lay down mandatory origin labelling as well as detailed traceability requirements for bovine animals and fresh, chilled or frozen beef products for the purposes of food safety, origin labelling and animal health including disease control. Operators at all stages of production up to the point of sale must have systems in place to ensure the link between bovine animals, carcasses and/or cuts of fresh, chilled or frozen beef including minced beef. In that respect, the following indications must be included on the label of such food products:

- a reference number or code linking the meat to an animal or group of animals;
- the approval numbers of the slaughterhouse and cutting plant;
- the Member State or third country of birth;
- the Member State or third country of rearing;

[116] OJ L 139, 30.4.2004, p. 55.

[117] Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).

[118] Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products (OJ L 216, 26.8.2000, p. 8).

- the Member State or third country of slaughter;
- the Member State or third country of cutting.

Where meat is derived from animals born, reared and slaughtered in the same Member State or third country, the indication may be given as 'Origin: [name of Member State/third country]'.Where beef is derived from animals that have been reared for 30 days or less, the indication of origin should provide:

- the Member State or third country of birth, or;
- the Member State or third country where slaughter took place;

Where full information is not available for beef imported from third countries, it may be permitted to state the country of origin as 'non-EU', provided that the name of the third country of slaughter is indicated. In this case, live animals must generally have been kept for a minimum of six months in the designated country before slaughter and export of the beef into the EU.

A derogation is allowed for minced meat where the label must indicate as a minimum 'Prepared: [name of Member State/third country]' to show where the minced meat was prepared; and 'Origin: [name of Member State/third country]' if the meat originated from a country or countries other than the country of preparation.

Traceability of processed beef meat is subject to the general requirements of Regulations (EC) No 178/2002 and 931/2011, which do not address the passing of origin information along the food chain.

d) Specific traceability requirements for sheep and goat meat

Council Regulation (EC) No 21/2004[119] concerns the identification and registration of live sheep and goats to permit individual traceability throughout their lifetime via electronic identification for animals born after 1 January 2010, subject to certain derogations.

The sheep and goat traceability system enables the complete traceability within the EU of live sheep and goats through individual electronic identification. Traceability, however, of unprocessed and processed sheep and goat meat is subject to the general requirements of Regulations (EC) No 178/2002 and 931/2011, which do not address the passing of origin information along the food chain.

In addition, national databases containing information on individual sheep and goat movements are not compulsory but may be implemented voluntarily in Member States. The lack of national databases makes full information on the origin of sheep and goat meat more difficult to access than in other systems, particularly traceability of unprocessed beef.

e) Specific traceability requirements for pig meat

Council Directive 2008/71/EC[120] concerns the identification and registration of live pigs. Pigs must be identified and registered in such a way that movements of animals and the farm of

[119] Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC (OJ L 5, 9.1.2004, p. 8).

[120] Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (OJ L 213, 8.8.2008, p. 31).

origin can be traced rapidly and accurately. The pig identification system is based on batch identification and not individual identification. In particular, Directive 2008/71/EC requires:

- identification marks to be applied before pigs leave the holding of birth, making it possible to determine the holding of origin;
- animal keepers must keep records of movements of animals entering and leaving a holding, at least on a batch basis and including the origin or destination, as applicable;
- keepers must supply the competent authority on request with all information concerning the origin, identification and where appropriate the destination of animals that they have owned, kept, transported, marketed or slaughtered;
- these procedures apply to intra-Union movements; and,
- pigs imported from third countries must be similarly identified and a link established and recorded to identify the third country. Imported animals going direct to a slaughterhouse need not be re-identified.

The pig identification and recording system enables identification of the holding and country of birth, and identification of the last holding from which an animal has come. Intermediate holdings may be traced through records of movements, although the system does not guarantee the traceability of all intermediate holdings prior to the last holding for individual animals. This system of traceability does not allow the passing of information on origin along the full chain.

Traceability, however, of unprocessed and processed pig meat is subject to the general requirements of Regulations (EC) No 178/2002 and 931/2011, which do not address the passing of origin information along the food chain. In addition, the national databases for pigs do not contain information on individual movements, making it more difficult to ensure the full origin information as regards pig meat, compared to the traceability of unprocessed beef.

5. Novel Food Regulation

The Novel Food Regulation (EC) n° 258/97 covers the food derived from animals which are obtained by non-traditional breeding techniques and therefore the food from cloned animals. As offspring and descendants are conventionally bred, their food is not covered by this Regulation.

Food from clones could only be placed on the EU market after the submission of an application -by an applicant to the competent Authorities of a Member State- has gone through a scientific risk assessment performed at national level and, if objections from member State(s), at EU level by the EFSA and finally obtained an individual authorisation by the European Commission. When a Novel Food authorisation is granted, mandatory labelling can be requested. Once an individual authorisation has been given to a prior applicant, other applicants can submit an authorisation request for the same product through a simplified procedure called "notification" based on the opinion of a national food assessment body that has established "substantial equivalence" with the novel food already authorised.

Based on an impact assessment report made in view of the revision of Novel Food Regulation, the 2008 Novel Food proposal provided for the simplification of legislation and of the administrative procedures for public Authorities and food business operators:

- The procedure for the assessment and authorisation of novel foods is fully centralised at EU level. National administrative procedures and double risk assessment -at national and most often at EU level (EFSA)-are repealed.

- The authorisation procedure is streamlined, increasing its efficiency and reducing the administrative burden and the length of the authorisation procedure.

- Individual authorisation currently granted only to the applicant are replaced by generic authorisations available to all food business operators which comply with the specifications of the authorisation.

- A simplified procedure for the placing on the market of the traditional foods from third countries is introduced to alleviate the administrative burden for their placing on the EU market.

However, the 2008 legislative proposal was not adopted in Conciliation in March 2011: a separate legislative proposal on Novel Food is planned to be adopted at the same time than the legislative proposal on cloning.

To date no application for authorisation of food from clones has ever been made. If an authorisation would be requested, it is likely that the authorisation would include a mandatory labelling of food from clones to ensure consumer information which implies that the cloned animals and their food will have to be traced. To date, the identification as such and the traceability of cloned animals is not in place.

ANNEX VII: BASELINE SCENARIO (ECONOMIC)

The scope of activities and sectors which may be impacted by measures on cloning covers the breeding sector, the farming sector (meat and milk production) and the food sector, covering five species (bovine, porcine, ovine/caprine and equine). The baseline is structured as follows:

A. EU livestock sector
B. The breeding sector
C. Food sector (including market outlook)

A. Livestock sector

1. EU livestock

Figures on the EU livestock for bovine, ovine, caprine are provided in table 1:

Table 1: EU livestock population – annual data – millions of animals)

ANIMALS	2010	2011	2012
Live bovine animals	87,3	86,2	85,9
Live goats	13,3	12,4	8,1
Live sheep	85,9	85,6	75,8
Live swine,	151,1	148,5	144,7

Source: Eurostat 2008

In 2007, EU livestock production accounted for 41% of agricultural output in value terms, representing 1.2% of the European Union's GDP. Highest GDP shares are found in Bulgaria, 4.4%, and Romania, 3.8%, while lowest shares are found in Luxemburg (0.5%), UK (0.6%) and Sweden (0.7%). In value terms, beef and milk represent over 50% of total output, with sheep meat representing over 20%[121]. However, the relative importance of livestock production per member states as expressed in the share of the agricultural output ranges from 28% in the case of Greece to 69% in Ireland, which is obviously at least partly the result of specific conditions.

Regarding number of actors across the meat and dairy supply chain, there are almost 8 Million farmers/producers and around 80.000 processors and the same amount of wholesalers and close to 700.000 food and specialist meat and dairy retailers across Europe.122

Dairy farming sector

[121] Eurostat data 2011
[122] Eurostat Structural Business Statistics (2009)

It remains characterized by an important diversity and heterogeneity in the EU27, despite strong restructuring, which expresses itself through labour input, the (feed) resource base and the intensification and specialization levels including a trend towards landless livestock production.

Meat farming sector

The EU produced 7,900 thousand tonnes of bovine meat for the purpose of food production in 2010 among which **2/3 originate from dairy herds and 1/3 from beef production**. Almost 60% came from four countries (France, Germany, Italy and the UK). The structure of EU production has changed little over time: the same four countries accounting for 57% of bovine meat production in 2004.

Pig production is generally an intensive, indoor, large scale business which combined with the much weaker dependence on the local resource base and bio-physical conditions leads to a relatively low level of variability in production systems.

Across the sector, the general trend in production continues to concentrate on fewer, larger farms. For example, in dairy production where about 50% of dairy cows are in herds of at least 50 heads and 85% of EU milk production is derived from high input/output production units.

Table 2: EU livestock sector's 2007 – economic output

Member state	**Livestock Production**				**Share (%) of livestock production(value terms)**				
	Million euro	Agricultural output share	GDP share		Milk	Beef	Pig meat	Sheep and goats	
fr	23542	36.4%	1.2%		31	34	12	3	
de	20400	45.1%	0.8%		47	15	25	0	
it	14441	33.5%	0.9%		30	23	16	2	
es	14296	*36.6%*	1.4%		19	15	33	11	
uk	12301	56.8%	0.6%		33	26	9	9	
nl	9140	*39.9%*	1.6%		43	18	22	1	
pl	8994	*45.5%*	2.9%		35	10	28	0	
dk	5449	*60.2%*	2.4%		27	6	44	0	
ro	4584	*34.7%*	3.8%		30	11	21	4	
Ie	4092	68.5%	2.1%		40	37	7	4	
Be	3799	52.0%	1.1%		25	27	34	0	
At	2883	48.0%	1.1%		33	29	23	1	
Gr	2881	27.9%	1.3%		37	8	9	27	
Pt	2499	37.9%	1.5%		30	20	19	5	
Hu	2296	35.4%	2.3%		22	5	28	2	
Fi	2259	55.2%	1.3%		46	15	15	0	
Se	2225	47.7%	0.7%		44	18	16	1	
Cz	1763	41.6%	1.4%		43	16	23	0	
Bg	1259	41.4%	4.4%		39	9	13	13	
Sk	941	48.9%	1.7%		31	13	21	1	
Lt	892	45.7%	3.1%		51	16	16	0	
Si	572	50.6%	1.7%		32	29	18	2	
Lv	411	43.4%	2.1%		49	11	15	1	
ᶜy	305	50.9%	2.0%		28	4	28	11	
Ee	303	48.2%	2.0%		55	8	22	1	
Lu	165	60.7%	0.5%		57	30	10	0	
Mt	71	59.5%	1.3%		24	6	22	1	
EU-27	**142190**	**41.4%**	**1.2%**		**34**	**20**	**21**	**4**	

Source: Eurostat 2008

Meat consumption
Forecasts are mainly driven by increasing poultry and pork meat consumption, as well as by a firm external demand and higher prices. On a per capita basis, EU meat consumption123 in 2022, at 82.6 kg, would be at approximately the same level as it was in 2009 and 1% lower than in 2011, despite the improved macroeconomic prospects. Pig meat is expected to remain the preferred meat in the EU with 40.8 kg/capita consumption in 2022, compared to 24.1 kg for poultry, 15.7 kg for beef/veal and less than 2.0 kg for sheep and goat meat.

2. International trade

The EU import trade in **live animals for food production** is fairly small except for horses. In 2011, **98%** of the €120m value of live animal imports for the species of interest here related to **horses** (generally originating in the US). Most, if not all, of these animals were destined for **sport and leisure** uses rather than food production.

3. Economics

Gross margins in the livestock sector are generally not high but they are positive. In the EU15 in 2007 farmers respectively i) breeders or ii) breeder and fatteners obtained on average comparable Gross Margin -including with EU and national coupled payments- of €310/cow and €297/cow respectively and an average of €135/male for fatteners (not directly comparable). The EU-10 margins were lower than the EU-15 for all three groups, which can be explained in part by the smaller number of cows/cattle per farm and lower prices for beef.

However, when looking at economic performance measured by Economic Profit (also taking into account estimates of the unpaid family labour) it is negative in most cases. Given the constraints and incentives, beef producers can be expected to adopt strategies of minimising production costs, underpaying family factors and subsidising farm production from decoupled payments and other sources of income124.

In the meat processing sector, the concentration process due to very low margins is continuing. For example, in Germany three slaughterhouses process more than 50% of all pigs. Similarly, in the retail sector, for the very same reason of decreasing profit margins, the concentration process is equally increasing with the top four retailers in Germany providing 65% of the total turnover of the sector.125

B. Breeding sector

1. Description

[123] Meat demand in Northern America and Europe would remain globally stable by 2050 but still remain highest in the world by 2050 at around 89 kg per inhabitant (against an estimated 83 kg in 2010); Source : Food and Agriculture organisation – livestock's long shadow – environmental issues and options (2006).
[124] European Commission 2011: EU beef farms report 2010', DG AGRI 2011

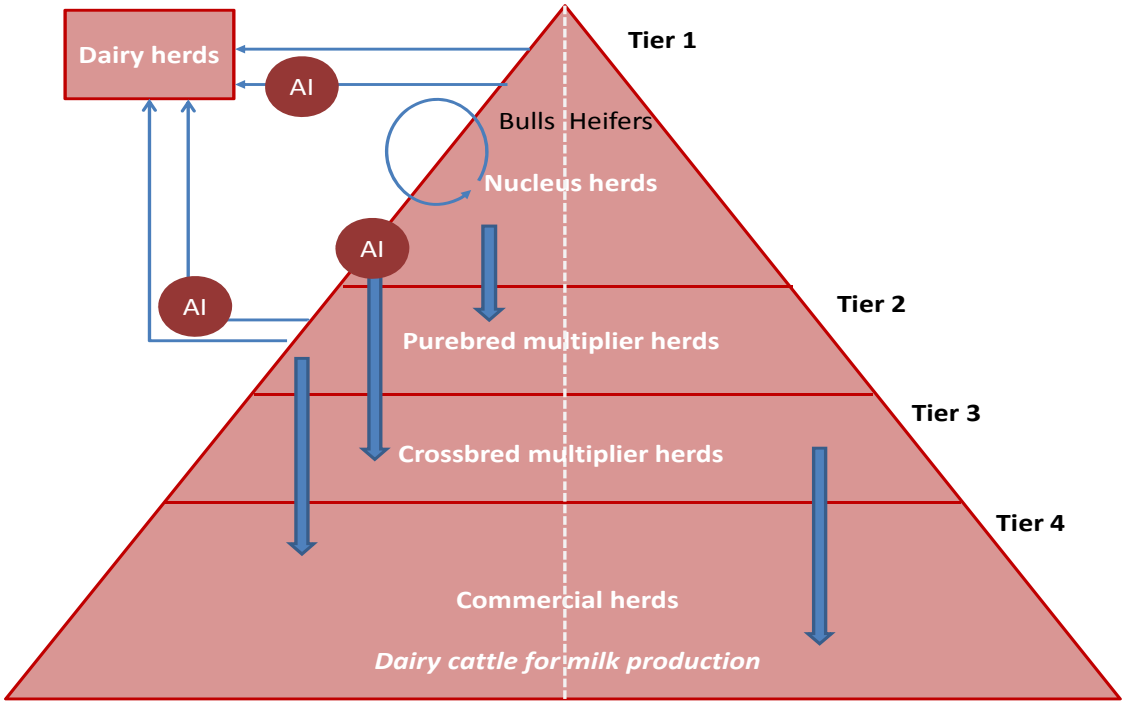
[125] DBV 2012: Situationsbericht 201/13 – Trends und Fakten zur Landwirtschaft', 2012

The structure of livestock breeding in Europe can be described as a pyramid with the elite or nucleus breeders at the top, one or more middle tiers of purebred or crossbred multipliers in the middle, and a final tier of commercial herds below. Most nucleus breeders and multiplier organisations are cooperatively owned by farmers, and are often SMEs organised in national umbrella organisations. For disseminating desired genotypes, these national or local organisations of farm owners are internationally co-ordinated by a small number of private, elite breeding companies and cooperatives.

Important terms are:

- **Nucleus herds:** elite breeders producing breeding stock, particularly males.
- **Multiplier herds**: take improved stock from nucleus herds to create larger number of animals for sale to tier below.
  - Purebred multipliers produce greater numbers of purebred animals, particularly males, for sale to the tiers below.
  - Crossbred multipliers producing crossbred animals, particularly females, for use in the commercial tier.
- **Commercial herds:** animals primarily involved in the production of milk and meat. Have little or no involvement in selling stock for further breeding.

Table 1: Beef and dairy breeding structure



Most nucleus breeders and **multiplier organisations** are cooperatively owned by farmers, and are often SMEs, operating in their native language, organised in national umbrella organisations. For disseminating desired genotypes, these national or local organisations of farm owners are internationally co-ordinated by a small number of private, elite breeding companies and cooperatives.

The **European Forum of Farm Animal Breeders** (EFFAB) reports that the livestock genetics industry mainly consists of '(small or) medium enterprises or small units in larger organisations.' According to one source, the size of livestock breeding companies tends to be medium scale, with at most 2000 employees, and annual turnovers not exceeding €0.5 billion[126].

Table 3: Economic operators in the EU by sector and species (indicative): General overview

Sector	All species	Bovine	Porcine	Ovine	Caprine	Equine
Companies that could conduct cloning activities	*7*	*4*	*1*	*0*	*0*	*2*
All companies	294	*150*	*50*	*10*	*5*	[79 studs]

Source: Eurostat 2008

AI companies, breeders and producers are often involved directly in **the import of reproductive materials and live animals**. Alongside those making direct use of the imported reproductive materials, live animals and products, there also exists a number of specialist import/export trading companies;

Globally, the main markets for **trade in bovine semen** are the EU, the US, Canada and Latin America. The **market value** of international trade in livestock genetics as a whole is relatively small: US and Canadian exports of bovine semen to the EU from 2006-11 were worth an annual average of €21 million and €17 million respectively.

Approximately 99% of **bovine semen** which is imported into the EU (around 1.9 million doses in 2011) are sourced from either the US or Canada. The US and Canada are also dominant in the markets for genetic materials of porcine, ovine, caprine and equine. A 2008 USDA report indicates that 'the largest U.S. export in livestock genetics is bovine semen'[127].

Parts of the EU livestock sector are now heavily reliant on **reproductive materials imported** from outside the EU. For example, while imported bovine semen represents **on average** 2.5% of the semen used in artificial insemination in the EU (considered much higher[128] in some Member States), the breeding sector considers access to this genetic material as essential to the continued viability of the industry[129].

On average, the EU exports of bovine are semen worth €25 million each year[130]. EU exports of bovine semen to the US, Canada and Latin America represent less than half of this total export value from 2006-2011. A further quarter of this trade is to neighbouring countries, particularly Turkey and Switzerland, while more modest amounts are exported to Australia, China and Japan.

[126] Gura, 2007
[127] USDA, 2008
[128] No data on national imports of reproductive material from third countries are available.

[129] ICF GHK report 2012
[130] Figures based on 2006-2011 COMEXT data

2. State of play on cloning activity

Taking into account that no cloning activity is taking place in the EU (see Annex III.1), it can be estimated that the economic viability of cloning depends mainly on the cost of a clone and the pregnancy rate: The higher the costs, the more likely the use of cloning remains restricted to long-use high output animals (dairy cows, race horses), the lower the costs, the more likely the use of offspring for short term use (e.g. beef production).

Commercial cloning activity in **third countries** is concentrated in a small number of countries. The countries with the most well-developed commercial cloning sectors are the US, Canada, and Argentina. New Zealand, Australia, Chile, China and Korea are also undertaking commercial cloning for livestock species.

- **Bovine animals**: commercial cloning activity for livestock is best developed in bovine animals. Cloning technology is being applied to cattle in the US, Canada, Argentina and Australia[131] It may also be undertaken in Brazil, New Zealand, Chile, China and Uruguay based on the presence of cattle cloning companies in these countries.
- **Milk and meat** from the offspring or descendants of cloned bovine animals have entered the food chain in the US and may have done so in Argentina; these are the products most likely to continue to enter human food chains in the near future. The Swiss government says that 'several hundred' second or third generation descendants of clones are in Switzerland (of a total 1.5 million head of cattle);[132]
- **Porcine animals**: consultations with the US cloning industry suggests that there is some commercial cloning for pigs in that country and that it is becoming more common. It may also be undertaken in New Zealand and China based on the presence of pig cloning companies in these countries.
- **Ovine and caprine animals**: consultations[133] with industry stakeholders in the EU of third country Competent Authorities indicate that commercial cloning of ovine or caprine animals outside the EU is uncommon. Some commercial cloning of these animals is on-going in the US, but at very small scale.
- **Equine animals**: consultations[134] of third country Competent Authorities indicate that there is no livestock cloning activity currently being conducted outside the EU for equine animals. Sport cloning is being undertaken in North and South America and Brazil and South Korea.[135]

Examples of on-going cloning activities:

- TransOva, a US cloning company estimates that it costs between USD 18,000-20,000 (approximately €15,000-16,000) to produce a clone. This range is likely to be competitive elsewhere in the world. Typically, clones are used as **breeding animals** due to their high cost. A clone can generate on average USD 60,000 in semen/embryo sales in the first year of production.

[131] DG SANCO survey to Member States and third countries regarding cloning activity, 2012
[132] Kanter, 2010
[133] See 5
[134] See 13
[135] Carroll, 2011

- Consultation with EU industry association COPA-COGEGA indicates that the cost of producing a clone for **research purposes** in the EU is approximately €12,000-15,000 (i.e. similar to the TransOva estimate). Embryos of cloned bulls sold at auction in the US have fetched USD 10,000-20,000 (€8,000-16,000), which is the same price as embryos from an animal from a 'non-cloned' high-value embryo line.
- A cloned **sport horse** can fetch USD 800,000 on the market, based on auction prices in Buenos Aires in 2010 for a cloned polo horse[136]. Cryozootech, a French horse cloning company sells a dose of semen from a cloned horse for between €450 and €700 depending on the clone.
- To produce the first **cloned fighting bull**, the Spanish breeders group May spent around €30,000. The family which owns the bull could expect to make around €1.5 million from selling the bulls that the clone fathers naturally during his lifetime.[137]

C. Food sector

1. General description

The EU food sector represents138 a total turn-over of 1,017 Billion € and approximately 287,000 companies employing 4.25 million people in the EU. Around 98 % companies are SMEs which represent around 49 % of total turn-over and 63% of employment in the sector.

It is the largest manufacturing sector in terms of turnover, value added and employment. It contributes for around 15 % of EU gross value added of manufacturing sector. The net trade balance was of 13.2 billion € in 2011 (see table 4 below).

Table 4: EU 27 data on Food and drink industry (Turnover, Number of employees, Trade)

	2010	2011	2011/2010(%)
Turnover (Euro billion)	953	1.017	+ 6,8
Number of employees (million)	4,25	4,25	0
Exports (Euro billion)	65,2	76,2	+ 16,6
Imports (Euro billion)	55,5	63	+ 13,5

The EU food sector for meat, milk and derived products is present at three stages of the food supply chain:

The first stage is composed:

[136] Carroll, 2011
[137] Kanter, 2010
[138]Sources "Data and Trends of the European Food and Drink Industry 2012" of FoodDrink Europe.

- for meat: slaughterhouses, cutting plants (primary and secondary cutting) and minced meat plants
- for milk: dairy farms, dairy plants (collect, storage, processing and packaging of milk and production of cheese and butter and milk industrial ingredients such as caseins).

The second stage is composed:

- for meat: meat processing (meat products), meat industrial ingredients (gelatine etc.) and all derived food products where meat is an ingredient
- for milk: processed milk products (yogurts, milk based specialities) and all food products which contain milk ingredients.

The third stage is composed:

- wholesalers, distributors and food retailers including food markets and direct sale at farms.
- caterers (canteens, restaurants etc).

2. Meat and milk sectors

- EU dairy sector

Dairy farming systems remain characterized by an **important diversity**, despite strong restructuring (the number of dairy holdings in the EU15 is now well below the one observed in France in the beginning of the 1970s), technical modernization and the wide adoption of the high yield races (Holstein).

The most striking aspect of the sectors **heterogeneity** is the substantial variation in size (surface, herd and quota), from small units (southern EU but also Austria) to large units (dominant in the UK, Denmark and the Netherlands). The heterogeneity also expresses itself through the natural production conditions, labour input, the (feed) resource base and the intensification and **specialization** levels and the trend towards landless livestock production.

The **average milk quota per farm** also varies strongly between dairy regions: Less than 160,000 kg in Austria, Spain, Italy, Finland, Portugal and south Germany (Bayern), milk quotas exceed 400,000 kg in the UK, Denmark, the Netherlands and Eastern Germany. A majority of total dairy holdings are relatively small in terms of cow numbers and contribution to total EU production. These farms are probably less specialised than those accounting for the majority of production with dairying being one of a number of enterprises (mainly other livestock enterprises) undertaken. However, to these farms dairying as an activity remains an important part of total economic activity.

EU dairy production is very stable, largely as an effect of the milk quota system, but this hides important trends. Due to the milk quota system, productivity gains in milk yields lead to a continuing reduction in the total number of dairy cows in the EU. In general, dairying in the EU continues to intensify and specialize, with herd sizes of individual farms increasing in all MS.

Together this means that production continues to concentrate on fewer, larger farms (e.g. about 50% of EU dairy cows are in herds of at least 50 heads) resulting in a corresponding decrease of dairy farming on many holdings and in some cases abandonment of holdings. This is true for virtually all dairy farms irrespective of system or bio-geographical region; noting that **85% of EU milk production is derived from high input/output** economic/technical class of dairy farming.

- EU meat sector

The EU produced:

- 7.844 million tons of **bovine meat** in 2011 (almost 60% came from France, Germany, Italy and the UK). It originates 2/3 from milk breeds and 1/3 beef breeds.
- 22.011 million tons of **porcine meat** in 2011 (almost 75 % came from Germany, Spain, France, Poland, Denmark and Italy).
- 0.732 million tons of **sheep meat** in 2011 (almost 75% from U.K., Spain, France and Greece)
- 0.059 million tons of **goat meat** in 2011 (almost 60% from Greece).
- 0.053 million tons of **horse meat** in 2008 (almost 75% from Italy and Poland).

3. International trade

- Meat sector

The EU exports **bovine and pork meat** mainly to Russia but also China, Japan, South Korea and Turkey. The EU is the 2nd biggest producer of pork meat (after China) and bovine meat (after USA) in the world. EU is self-sufficient for pork and poultry and has a deficit for bovine (3-4%), ovine (20-22%) and horse (80%) meat.

- Beef and veal

The EU is a **net importer of beef** which is mainly imported from:

- South America (mainly Argentine, Brazil, Uruguay) with a significant decrease trend.
- USA with significant increase trend following extension of EU import quota in context of new EU-US agreement on hormone free beef production for EU (20.000 tonnes).

Beef imports are forecast to increase. The trade in beef products could reach half a million tonnes by 2020. Market effects (e.g. price changes) are more likely to be observed where measures have an impact on these trade flows. In 2011, approximately 300,000 tonnes of bovine meat products worth over €1.7 billion were imported into the EU. More than 95% of these imports came from eight countries. Argentina, Brazil and Uruguay accounted for approx.70% of total trade volume

In recent years, Australia, New Zealand, Paraguay, Namibia and the US all increased their bovine product exports to the EU. By 2011 these five countries together accounted for 27% of total trade (5% in 2006).

EU beef and veal imports are forecast to increase by 10% from 2011 to 2020 according to the latest projections (OECD-FAO, 2012). Globally, the EU is the third largest importer of beef and veal behind Russia and Japan.

In total, EU imports of beef, veal, dairy products and sheep meat are worth € 3.3 billion per year.

Table 6: Overview annual value of EU imports

Species	Product	Approximate Total Annual Value	Summary
Bovine	Beef and veal products[139]	€ 1.7 billion	The EU is a net importer of bovine meat products and the third largest importer in the world; the net trade imbalance is expected to grow to 2020
	Cheese and butter	€ 610 million	The EU imports considerable quantities of cheese and butter despite being a net exporter of these products
Ovine	Sheep meat	€1 billion	The volume of imported sheep meat is equivalent to over a quarter of domestic EU production; 85 per cent was supplied by New Zealand; the EU is a net importer of sheep meat

Source based on COMEXT data

Table 7: Import sector overview: Number of importers

Sector	All species	Bovine	Porcine	Ovine	Caprine	Equine
Importers: live animals	1667	3	12	5	2	1645
Importers: meat	715	280	40	374 (sheep and goat)		*21*

Source: Eurostat 2008

- Porcine meat

The **EU is self-sufficient in pig meat** and EU porcine production is stable. The EU consequently imports relatively little (approximately 15,000 tonnes per year). It accounts for less than 0.1% of global imports. In 2011, the EU imported just 14,000 tonnes of pig meat, and a further 18,000 tonnes of offal at a total value of €61 million. 99.9% of pig offal was imported from Switzerland; over 80% of imported pig meat came from the US and Chile. The EU also imports relatively high quantities of low value prepared pig meat such as ham and sausages and offal products; On average the EU imported 126.000 tonnes of such products at an approximate value of € 18 million per year from 2006-2011.
In addition, the EU also imports gelatine for EU food, cosmetics and pharmaceutical industries. Total annual EU imports of gelatine are relatively stable, with 20,000 tonnes imported annually over the period 2006-11, valuing at approximately €76 million per year.

- Ovine and caprine meat

The EU is a net importer of ovine and caprine meat (23% of EU production). Imports from New Zealand and Australia are the most important trades for ovine and caprine products. From 2006-2011, EU imports of sheep meat were valued at just over €1 billion per year

[139] Value includes all fresh, frozen, chilled, prepared and preserved bovine meat, offal and derived products including gelatine

(averaging 210,000 tonnes per year). Of the total volume imported into the EU over this period, 85% of total sheep meat imported was supplied by New Zealand at an average of 178,000 tonnes each year. A further 8% of EU sheep meat imports were sourced from Australia. Though these figures are relatively low, it is notable that the volume of imported sheep meat is equivalent to over 25% of domestic EU production.

Table 8: Overview annual value of EU imports

Species	Product	Approximate Total Annual Value	Summary
Caprine			
Ovine	Sheep meat	€1 billion	The volume of imported sheep meat is equivalent to over a quarter of domestic EU production; 85 per cent was supplied by New Zealand; the EU is a net importer of sheep meat

Source based on COMEXT data

- Horse meat

The EU is a net importer of horse meat (50% of EU production). In 2011, the EU imported 28,000 tonnes of horse meat, valued at €94 million. The volume of imported horse meat is equivalent to over 50% of domestic EU production. From 2006-2011, the EU imported a total of €592 million worth of horse meat, 60% of which was sourced from Latin America (Argentina, Brazil, Uruguay and Mexico) and a further 38% from Canada and the US.

- Dairy sector

The EU **is largely self-sufficient in dairy products**. It is **a net exporter** but still imports considerable quantities of cheese from third countries and, to a lesser extent, butter. These two product groups accounted for almost 90% of the €610 million average annual value of EU dairy imports from 2006-2011.

The EU is a major player in **international dairy markets**. It accounted for 24-30% of world dairy exports from 2005-2010. The big four dairy producers in order of their market share are New Zealand, the EU, Australia and the US. Over half of all EU imports of cheese in 2006-11 were purchased from Switzerland, representing 70% per cent of the total value of EU cheese imports (€1.79 billion). In this period, a further 150,000 tonnes of cheese worth €348 million were shipped to the EU from New Zealand. In the same period, New Zealand was also the source of 88% of all EU butter imports, at the average annual value of €110 million from 2006-2011.

Imports of milk proteins and caseinates were also significant over this period, with the EU on average importing €178 million each year from 2006-11. Of this total amount, 80% was sourced from just three countries: New Zealand, Ukraine and Belarus.

4. Outlook all markets

The **EU meat market** is likely to be affected by the on-going economic downturn and historically high levels of unemployment, which tend to push EU demand towards cheaper meat options. The new animal welfare requirements in the pig sector are also expected to play an important role in the near future. As a consequence, total EU meat production, after having increased during both 2010 and 2011, will contract by 2% over the next two years.

The OECD-FAO Agricultural Outlook (2011) forecasts that EU exports in beef and veal will fall steadily year-on-year from 2010 to 2020, dropping by an estimated total of 41% over the period. EU beef accounts for only 3% of global beef and veal exports. The marginal role of the EU in these markets is expected to continue to 2020. Major third country beef exporters include Australia, Canada, India, the US, and the South American countries of Brazil, Argentina and Uruguay. Brazil, Uruguay and Australia are also major global suppliers of live bovine animals, exporting to the EU's main markets in North Africa and the Middle East.

The **net trade position** of the EU is projected to deteriorate over the outlook period, driven by an increase in meat imports (of beef/veal, sheep and goat and poultry meats) and a parallel decline in exports of poultry. Aggregate meat imports would grow by 5.2% (2022 vs. 2011) and exports would decline by 6.8%, leaving the EU, nevertheless, a net exporter of pig and poultry meats in 2022.

The **EU milk production** is projected to continue increasing from 2012 onwards, at a moderate growth rate. Aggregate EU production would remain below the potential growth rate provided by the gradual elimination of the quota regime. EU milk production is projected to reach 159.3 million tonnes in 2022, accounting for a cumulative increase of 5% since 2011.

Medium term prospects for **milk and dairy products** appear favourable due to the continuing expansion of world demand. Global population and economic growth, and increasing preference for dairy products are expected to be the main drivers, fuelling EU exports and sustaining commodity prices. The best export performance is shown by cheese and SMP, whose exports over the outlook period would expand by two thirds and triple respectively.

While the global market situation has recently been favourable, DG AGRI (2011) reports that expectations for the next two years depend on the extent of increased milk production both in the EU and in the main supplying countries (e.g. New Zealand, Australia, and the US) and the sustainability of strong demand on the world market led by China and other countries of South-East Asia as well as by the Near and Middle East.

The OECD-FAO Agricultural Outlook (2011) projects that global imports of dairy produce will rise by a million tonnes from 2010 to 2020. Despite this growth in the market the EU's share of global dairy products is forecast to fall below 20% in this period. This is largely as a result of competitive pressure from New Zealand.

From 2009 to 2010, **EU bovine exports** increased in volume by 125%. Particularly marked increases occurred in the trade of fresh, chilled and frozen bovine meats as well as in the trade of live bovines. From 2004-2011, the relatively stable EU exports in bovine offal represented 25% of total bovine meat and meat product exports. As a result of such rapid growth, the total value of EU exports of live bovines and bovine meat in 2011 was worth of €1.7 billion. Exports doubled in size in a single calendar year from 2009 to 2010.

EU porcine export market outlook: pig meat accounted for roughly a quarter of total world pig meat exports from 2005 to 2010. Pork exports from the US and Canada accounted for a further quarter each in this period; Brazil is the fourth largest pork exporter.

EU pig meat exports are forecast to decline year on year to 2020, with the EU seeing its share of the market fall to 20% (OECD-FAO 2011). This decline is likely to occur in the context of global growth in the volume of pig meat exports (likely to be sustained by demand in Japan, Russia, Ukraine and other East Asian markets), which is forecast to be mostly captured by US pig exporters. There is also growing import demand for pig meat in markets where EU exports currently have less market presence such as Mexico, the US and Australia.

Looking ahead for the **EU ovine and caprine export market** to 2020, the forecast to increase but still account for just 2% cent of global sheep meat exports (OECD-FAO 2011). Australia and New Zealand together account for over 75% of this trade. The EU is the world's biggest importer of sheep meat, taking 25% of global sheep imports in 2010. Saudi Arabia, the US and China are the next biggest markets for sheep imports. The volume of EU imports of sheep meat is forecast to decline by 22% from estimated 2010 levels.[140]

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[140] ICF GHK 2012 page 34

ANNEX VIII: EU STATISTICS ON IMPORTS OF LIVE ANIMALS, REPRODUCTIVE MATERIALS, MEAT, MEAT PRODUCTS, MILK AND MILK PRODUCTS (SOURCES COMEXT[141] AND TRACES[142])

Statistics on imports below provide from 2 EU sources (Comext and TRACES) and may differ between the 2 sources. Data of reference are those from Comext. TRACES data are provided as a complement and should be considered mainly for the imports of live animals and reproductive materials.

The discrepancy in the trade volumes between Eurostat and TRACES data for the products of animal origin is due to the different methodology applied for the definition of the products group (meat, milk etc.). The custom code applied for the custom tariff purposes do not take account the veterinary description of the goods. For example, in case of the custom code applied for the meat products allows the use of the added salt, whereas such products under veterinary legislation is categorised as meat preparations.

In case of data differences for the reproductive material, there is no conventional rate of duty applied for the import and reproductive material is not presented as unit volume as straw, but converted as a weight calculated number of straws. The TRACES data are recorded by Member State border veterinarian and in such cases as well different volume measurements have been applied: number of straws, amount presented in kilograms, amount presented in ml etc.

I. Live animals

Importations of live bovine in the EU are very low apart from Turkey in 2011. The EU also imports few bovines in a sporadic way from various third countries including Canada and USA.

The same situation occurs for imports of live ovine and caprine. Imports of live porcine though limited are more significant and originate mostly from Canada and Russian Federation.

Imports of live horses are more developed and originate from a large set of countries. On the contrary to other above species where imported animals are intended for reproduction, live horses are mainly imported for horse races and leisure activities.

[141] Comext: is a statistical database on trade of goods managed by Eurostat, the Statistical Office of the European Commission.

[142] TRACES: is a management tool for tracking the movement of animals and products of animal origin from both outside of the European Union and within its territory.

- EU live bovine imports compared to EU livestock (Source Comext)

Origin/Year/Nbr. Anim.	2007	2008	2009	2010	2011
Turkey	0	0	0	6	18.548
Albania	0	0	67	0	0
FYROM	0	62	0	0	0
Canada	1	0	0	10	42
Croatia	0	0	14	10	0
United States	0	15	0	0	0
Ukraine	3	0	0	0	0
Argentina	2	0	0	0	0
United Arab Emirates	0	1	0	0	0
New Zealand	0	0	0	0	0
TOTAL	**6**	**78**	**81**	**26**	**18.590**
EU live bovines	89.037.000	88.867.000	88.300.000	87.391.200	86.250.200
% of imports/EU production	0.000006	0.00008	0.00009	0.00003	0.021

- EU live bovine imports (Source TRACES)

Origin/Year Nbr. Anim.	2006	2007	2008	2009	2010	2011
Canada	0	0	0	0	10	42
New Zealand	0	0	0	0	0	3
TOTAL	**0**	**0**	**0**	**0**	**10**	**45**
EU live bovines	N/A[143]	89.037.000	88.867.000	88.300.000	87.391.200	86.250.200
% of imports/EU production	--	0	0	0	0.00001	0.00005

[143] N/A: not available

- EU live ovine imports (Source Comext)

Origin/Year **Nbr. Anim.**	**2007**	**2008**	**2009**	**2010**	**2011**
Turkey	0	0	0	0	25.690
Bosnia and Herzegovina	0	631	0	0	0
Croatia	20	0	0	510	0
New Zealand	2	5	0	10	29
Canada	0	0	11	21	0
Russian Federation	0	0	0	0	7
Iceland	5	0	0	0	0
TOTAL	**27**	**636**	**11**	**541**	**25.726**
EU live ovines (source Eurostat)	95.803.000	90.907.000	88.757.000	85.945.500	85.648.000
% of imports/EU production	0.00002	0.0006	0.00001	0.0006	0.03

- EU live ovine imports (Source TRACES)

Origin/Year **Nbr. Anim.**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
New Zealand	0	2	21	0	22	29
Croatia	0	0	0	0	510	0
Canada	0	0	0	11	9	0
TOTAL	**0**	**2**	**21**	**11**	**541**	**29**
EU live ovines (source Eurostat)	N/A	95.803.000	90.907.000	88.757.000	85.945.500	85.648.000
% of imports/EU production	--	0.000002	0.00002	0.00001	0.0006	0.00003

- EU live caprine imports (source Comext)

Origin/Year **Nbr. Anim.**	**2007**	**2008**	**2009**	**2010**	**2011**
Bosnia and Herzegovina	0	55	0	0	0
Chile	0	0	0	44	0
Canada	16	0	0	0	0
Russian Federation	0	1	3	0	0
United States	0	0	0	0	1
TOTAL	**16**	**56**	**3**	**44**	**1**
EU live caprine **(source Eurostat)**	13.212.000	11.430.000	12.920.000	13.364.800	12.480.700
% of imports/EU production	0.0001	0.0004	0.00002	0.0003	0.000008

- EU live caprine imports (source TRACES)

Origin/Year **Nbr. Anim.**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
New Zealand	0	0	0	0	0	6
Croatia	0	0	0	4	0	5
Chile	0	0	0	3	0	0
Canada	23	16	0	1	0	0
TOTAL	**23**	**16**	**0**	**8**	**0**	**11**
EU live caprine (source Eurostat)	N/A	13.212.000	11.430.000	12.920.000	13.364.800	12.480.700
% of imports/EU production	--	0.0001	0	0.00006	0	0.00008

- EU live swine imports (Source Comext)

Origin/Year **Nbr. Anim.**	**2007**	**2008**	**2009**	**2010**	**2011**
Russian Federation	135	792	1.639	1.382	170
Canada	623	517	449	346	88
United States	87	126	106	88	7
Albania	42	0	0	0	0
Belarus	20	0	0	0	0
TOTAL	**907**	**1.435**	**2.194**	**1.816**	**265**
EU live porcine (source Eurostat)	159.965.000	152.988.000	151.911.000	151.130.100	148.556.500
% of imports/EU production	0.0005	0.0009	0.001	0.001	0.0002

- EU live porcine imports (Source TRACES)

Origin/Year **Nbr. Anim.**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Canada	254	324	611	727	551	845
TOTAL	**254**	**324**	**611**	**727**	**551**	**845**
EU live porcine (source Eurostat)	N/A	159.965.000	152.988.000	151.911.000	151.130.100	148.556.500
% of imports/EU production	--	0.0002	0.0003	0.0004	0.0003	0.0005

- EU live equine imports (source Comext)

Origin/Year **Nbr. Anim.**	**2007**	**2008**	**2009**	**2010**	**2011**
United States	3.679	3.551	3.090	2.359	2.256
Argentina	3.036	2.561	1.589	1.308	789
Belarus	2.637	1.910	1.154	518	16
Iceland	1.135	1.399	1.445	961	915
Croatia	627	397	275	656	898
Uruguay	790	449	421	248	26
United Arab Emirates	363	249	230	290	184
Canada	311	279	169	122	116
Ukraine	546	24	27	19	11
Morocco	322	46	36	59	92
Russian Federation	105	139	86	126	83
Montenegro	0	0	0	0	500
Australia	130	104	92	71	65
Brazil	112	139	38	62	27
New Zealand	127	81	34	42	58
TOTAL	**26.327**	**10.606**	**7.403**	**6.081**	**9.287**
EU live equine (DG Sanco website)	6.000.000	6.000.000	6.000.000	6.000.000	6.000.000
% of imports/EU production	0.4	0.1	0.1	0.1	0.1

- EU live equine imports (source TRACES)

Origin/Year **Nbr. Anim.**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
United States	2407	3094	2896	2364	1986	6530
Argentina	2472	2615	2594	1604	1409	904
Iceland	1163	1237	1452	1230	970	561
United Arab Emirates	533	375	385	380	407	473
Qatar	31	84	95	70	127	156
Russian Federation	122	156	192	112	229	141
Belarus	4255	2493	1913	1193	475	31
New Zealand	142	154	110	41	66	95
Australia	187	168	198	165	106	47
Uruguay	320	425	482	421	301	69
Brazil	125	85	188	59	139	74
Morocco	313	344	76	97	90	110
TOTAL	**12070**	**11230**	**10581**	**7736**	**6305**	**9191**
EU live equine (DG Sanco website)	6.000.000	6.000.000	6.000.000	6.000.000	6.000.000	6.000.000
% of imports/EU production	0.2	0.18	0.17	0.1	0.1	0.15

II. Semen and embryo

The EU imports significant amounts of bovine semen doses mainly from USA, Canada and to a lesser extent from New Zealand, Australia, Switzerland and Norway. Imports from these countries are well established for many years and are growing regularly (with high growth trend for imports from New Zealand and Norway).

Imports of bovine semen do represent on average 2.5 % of the total amount of semen doses used in the EU. However, this low percentage does not reflect their importance in EU breeding schemes as imported semen is of high genetic value for the dairy production.

Imports of porcine semen are more limited than for bovine: the use of frozen porcine semen is very limited as the number of piglets obtained with frozen semen is far lower than with fresh semen. However some trade of frozen porcine semen of high genetic value takes place and originates mostly from Canada and USA.

Imports of ovine and caprine semen are very limited and originate mostly form USA, Canada, Australia and New Zealand. Though import figures are low, they may be significant both in terms of percentage and genetic value as the use of artificial insemination for ovine and caprine in the EU is very limited compared to its use for bovine specie.

- EU bovine semen imports in doses (Source Comext)

Origin country / Year / Dosis	**2007**	**2008**	**2009**	**2010**	**2011**
United States	3.418.197	3.553.153	3.678.915	4.283.701	4.241.689
Canada	2.453.611	2.670.217	2.613.608	3.380.888	3.610.052
New Zealand	39.840	1.800	66.294	413.371	574.755
Australia	41.933	78.283	39.142	44.446	28.778
Croatia	0	0	5.010	21.000	103.011
China	0	0	60.000	7.701	0
Serbia	0	9.000	0	0	0
Philippines	4.829	0	0	0	0
Costa Rica	0	0	3.000	0	0
Venezuela	0	1.800	0	0	0
Malaysia	500	0	0	0	0
Argentina	0	0	0	0	36
TOTAL	**5.958.910**	**6.314.253**	**6.465.969**	**8.151.107**	**8.558.321**

- EU bovine semen imports in doses (Source Traces)

Origin country / Year / Dosis	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
United States	115537	171256	724156	716299	817718	977402
Canada	81963	172686	478279	557304	661156	898107
Australia	7384	5832	11897	7395	11311	2225
New Zealand	18549	297	14	1418	664	803
Croatia	0	0	0	13	1000	84
Chile	20692	0	0	2	0	0
Argentina	4896	0	780	0	0	0
China	0	0	14036	0	0	0
India	0	36410	46669	0	0	0
TOTAL	**248.967**	**386.505**	**1.275.083**	**1.281.962**	**1.492.000**	**1.878.600**

- EU porcine semen imports in doses (Source Traces)

Origin country / Year / Dosis	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Canada	9	210	373	200	782	176
United States	280	517	5	75	173	59
Australia	127	126	0	16	0	0
New Zealand	10414	0	0	0	0	0
South Africa	0	0	73	0	0	0
TOTAL	**10830**	**853**	**451**	**291**	**955**	**235**

- EU equine semen imports in doses (Source Traces)

Origin country / Year / Dosis	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
United States	725	174479	5898	3119	7427	260772
Canada	523	1442	2895	99	42	286
Brazil	0	0	0	0	0	80
Australia	0	27	0	67	11	3
New Zealand	0	0	0	0	2	2
Morocco	0	0	0	30	0	1
United Arab Emirates	0	0	0	19	1	0
Mexico	15	0	0	13	0	0
Argentina	0	30	18	0	0	0
Tanzania	0	0	1	0	0	0
TOTAL	**1263**	**175978**	**8812**	**3347**	**7483**	**261144**

- EU semen imports (ovine and caprine) in doses (Source Traces)

Origin country / Year / Dosis	2006	2007	2008	2009	2010	2011
United States	469	1685	535	385	572	912
Canada	79	7	82	128	317	267
Australia	312	586	265	63	177	242
New Zealand	83	18	23	1763	14	14
Japan	1	0	2	22	210	0
South Africa	0	0	29	51	28	0
Brazil	0	1	0	0	0	0
TOTAL	**944**	**2297**	**936**	**2412**	**1318**	**1435**

Imports of bovine embryo take place on a regular basis and are reducing since 2009. They originate mostly from Canada and USA. No figures are available for other species.

- EU bovine embryo imports (Source TRACES)

Origin country / Year / Quantity (number of embryos)	2006	2007	2008	2009	2010	2011
Argentina	0	0	0	2	0	1
Australia	81	6	106	37	104	64
Canada	2008	3008	2165	3934	3762	2955
New Zealand	0	16	0	0	0	1
Philippines	0	0	1	0	0	0
Turkey	0	0	0	0	1	0
United States	2670	2924	3402	2959	2613	2494
TOTAL	**4759**	**5954**	**5674**	**6932**	**6480**	**5515**

III. Meat, meat products, milk and milk products

1 Meat and meat products

Imports of bovine meat originate from a wide range of countries. More than 95 % of these imports come from 9 countries (Brazil, Argentina, Uruguay, Botswana, New Zealand, Namibia, United States, Australia, Paraguay) and imports from Brazil, Argentina, and Uruguay represented around 80 % of the total trade volume in 2010. These imports are on a slow growing trend, except for USA where there are in major increase since 2010.

Imports of swine meat originate mainly from Chile, United States, Brazil, Australia and Canada. There is no general trend as they have increased from Brazil, Australia and decreased from Chile, USA, Argentina, New Zealand.

Imports of ovine and caprine originate mostly from New Zealand (around 80 %), Australia (around 10 %) and Chile, Argentina, Uruguay and Macedonia (around 10 %). Figures are common for ovine and caprine imports but caprine imports are very limited. There is no significant trend as the EU is importing the vast majority of its ovine consumption since the last decade.

- EU bovine meat imports in tons (source Comext)

Origin country / Year / Quantity	**2007**	**2008**	**2009**	**2010**	**2011**
Brazil	181.594	41.951	40.449	43.578	45.390
Argentina	57.595	56.168	73.578	50.168	44.780
Uruguay	25.252	46.441	58.289	47.537	39.001
Australia	6.310	8.952	10.770	9.556	12.480
Namibia	8.051	7.960	9.674	10.440	6.904
United States	2.061	4.943	7.394	11.753	16.171
New Zealand	2.592	7.870	10.465	9.607	11.169
Botswana	10.452	7.855	8.669	12.090	736
Chile	2.099	1.832	2.343	1.861	1.663
Paraguay	0	168	1.823	3.671	3.184
Serbia	2.322	1.777	984	1.122	784
Croatia	1.067	1.287	1.185	1.152	1.505
Canada	883	679	572	551	707
TOTAL Beef Total bovine meat	 297.582 N/A	 188.569 391.800	 226.504 425.600	 203.429 369.900	 184.694 N/A
EU production Beef Total bovine meat (source Eurostat)	 6.113.00 8.204.000	 6.050.000 8.072.000	 5.612.000 7.717.000	 5.716.000 7.918.000	 N/A 7.844.000
% imports/EU production Beef Total bovine meat	 4,86 % --	 3,11 4,85	 4,03 5,51	 3,56 4,67	 -- --

- EU bovine meat imports in tons (sources TRACES)

Origin country / Year / Quantity	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Brazil	173974	200977	61276	40560	56668	88765
Argentina	7995	24159	34354	39357	49180	48007
Uruguay	11644	16361	46823	41357	39119	43046
New Zealand	2315	4592	9971	10770	10457	28857
Australia	9109	7331	9700	8189	7826	27114
United States	242	1639	4555	3109	9292	15694
Namibia	4030	5409	7728	9295	9044	10344
Paraguay	0	0	144	1069	5324	3173
Canada	526	759	673	555	528	2452
Chile	1062560	1187896	671837	1206082	1597986	1763572
Croatia	644854	1065554	1303234	1232284	1179209	1555919
Serbia	0	1991161	1778254	978283	1126053	796406
Botswana	4253350	7212455	6517167	10529026	11037246	689238
Swaziland	0	74982	268720	190695	328487	38869
Serbia and Montenegro	1893666	349895	0	0	0	0
South Africa	1962395	1000	3034	0	0	0
Syrian Arab Republic	0	21951	0	0	0	0
Thailand	0	12518	25641	0	0	0
Uganda	0	11041	50459	0	0	0
Viet Nam	23130	12013	35343	0	0	0
TOTAL	**10049790**	**12201693**	**10828913**	**14290631**	**15456419**	**5111456**

- EU porcine meat imports in tons (source Comext)

Origin country / Year / Quantity	**2007**	**2008**	**2009**	**2010**	**2011**
Chile	12.323	17.142	16.554	8.875	7.105
United States	9.979	22.951	7.147	6.222	2.598
Australia	1.923	1.557	879	1.234	1.736
Japan	110	94	1.693	48	53
Russian Federation	98	141	946	58	109
South Korea	160	3	158	66	327
Canada	0	0	295	350	5
Belarus	148	0	60	190	97
Croatia	22	50	70	22	61
China	0	17	146	0	24
Hong Kong	0	0	158	28	0
Brazil	130	23	0	0	0
Ukraine	0	0	39	47	20
TOTAL	24.893	41.978	28.145	15.140	12.135
EU porcine meat production (source Eurostat)	N/A	22.574.000	21.279.000	22.011.000	22.388.000
% imports / EU porcine meat production	--	0.19%	0.13%	0.07%	0.06%

- EU swine meat imports (source TRACES)

Origin country / Year / Quantity (kg)	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Brazil	28757737	27461301	19959328	22456542	40669925	34722611
Chile	1808137	9181850	10335403	10454470	12321828	6589425
Australia	299575	737652	649168	326483	1306825	3371357
United States	6709709	27363029	21490418	6710900	4416382	2486045
Argentina	5655380	4626748	1220232	2991189	2033793	1624437
Croatia (Local Name: Hrvatska)	691875	794008	1030038	645050	1212180	1278558
New Zealand	45602	187024	615579	245574	159525	109116
Uruguay	42779	94266	222218	631154	2073887	106583
Canada	50955	37067	41310	142883	315379	61318
Thailand	156804	84934	23301	67186	149424	39748
Serbia	0	0	0	13152	23337	20000
Botswana	0	0	0	0	18701	18268
South Africa	0	43191	109168	4155	567	0
TOTAL	**44218553**	**70611070**	**55696163**	**44688739**	**64701753**	**50427466**

- EU ovine and caprine meat imports in tons (source Comext)

Origin country / Year / Quantity	**2007**	**2008**	**2009**	**2010**	**2011**
New Zealand	191.693 217.921	189.432 432.800	185.174 229.746	164.348 197.043	149.224
Australia	16.920	18.057	17.645	14.585	16.639
Argentina	4.646	4.548	5.912	4.796	3.605
Chile	4.072	3.376	5.104	5.278	4.749
Uruguay	3.627	3.557	3.426	2.709	2.994
FYROM	2.605	2.346	2.598	2.173	2.574
Iceland	517	829	1.404	1.872	1.210
Falkland Islands	321	298	322	327	396
TOTAL	**442322**	**655243**	**451331**	**393131**	**181391**
EU ovine / caprine meat production	**N/A**	**1.022.000 (945+77)**	**808.000 (748+60)**	**786.000 (725+61)**	**791.000 (732+59)**
% imports / EU ovine and caprine production	--	64.1%	55.8%	50%	22.9%

- EU ovine and caprine meat imports (source TRACES)

Origin country / Year / Quantity (kg)	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
New Zealand	169241349	207819306	421658085	218614718	186705599	237765575
Australia	15753193	15940698	38283820	19722278	15058534	19939478
Chile	1016565	1456320	1979460	2300314	3500822	4863268
Argentina	2025915	2204192	2798619	3913173	3784742	3373474
Uruguay	2215407	2328314	3629467	2788308	2545345	2803375
FYROM	2299000	2164609	2274887	2630773	2365727	2529928
Iceland	475934	400907	905287	941638	1519615	1199528
Falkland Islands (Malvinas)	235899	249602	300086	293021	284397	411320
Greenland	591	793	10302	867	770	1343
United States	33476	64362	28903	22376	0	807

Brazil	56447	187702	0	11829	127113	0
TOTAL	**193353776**	**232816805**	**471868916**	**251239295**	**215892664**	**272888096**

- EU horse meat imports in tons (source Comext)

Origin country / Year / Quantity (Tons)	**2007**	**2008**	**2009**	**2010**	**2011**
Argentina	16.414	13.277	11.921	8.767	7.300
Canada	7.442	13.727	10.114	9.126	8.874
Brazil	11.636	8.449	8.464	2.774	1.602
Mexico	4.327	6.758	7.037	7.404	5.430
Uruguay	2.785	2.957	3.034	2.422	2.884
United States	3.983	1	0	211	2.038
Australia	542	407	1.305	324	120
New Zealand	142	135	116	150	64
Iceland	13	36	46	26	0
TOTAL	47.284	46.000	42050	31204	28312
EU horse meat production (Source Eurostat)	56.000	53.000	N/A	N/A	N/A
% imports / EU horse meat	84.4%	87 %	--	--	--

IV. Milk and milk products

The EU does import very limited quantities of fresh milk (for dairy plants at EU borders). Therefore data on imports can be assumed as referring to milk products (including milk powder for further processing).

Milk products imports originate mostly from Switzerland, New Zealand, USA and Australia.

- EU milk imports in tons (source Comext)

Origin country / Year / Quantity (Tons)	**2007**	**2008**	**2009**	**2010**	**2011**
Croatia	8.623	4.613	13.430	2.697	2.944
FYROM	1.302	659	384	0	1
Lebanon	0	0	0	0	773
Australia	546	48	50	55	1
Japan	0	0	191	2	0
United States	3	86	6	0	0

Russian Federation	0	2	8	20	20
United Arab Emirates	0	0	0	0	43
TOTAL	10474	5408	14069	2774	3782
EU milk production*	N/A	46.351.000	46.056.000	46.592.000	46.918.000
(source Eurostat)	N/A	47.994.000	47.749.000	48.253.000	48.657.000
% imports / EU milk production	--	0.011%	0.03%	0,005 %	0.008%

* liquid milk and cream

- EU milk products* imports in tons (source Comext)

Origin country / Year / Quantity (Tons)	**2007**	**2008**	**2009**	**2010**	**2011**
New Zealand	111.406	73.860	84.799	63.723	50.479
United States	16.832	18.972	1.491	7.570	10.693
Australia	14.008	9.817	6.828	4.210	2.773
Canada	6.609	6.832	3.487	2.082	40
Croatia	4.562	3.248	2.405	2.621	2.764
Israel	918	818	3.254	948	1.003
Belarus	2.233	229	1.140	79	0
Iceland	288	782	477	545	740
Algeria	221	236	32	164	276
China	41	247	152	80	172
Malaysia	26	645	1	0	1
Russian Federation	29	85	60	330	51
Morocco	41	21	246	200	0
TOTAL	157.214	115.792	104.372	82552	68.992
EU milk products* production (source Eurostat)	N/A	12.775.000	12.766.000	12.686.000	12.878.000
% imports / EU milk products production	--	1.96%	1.84%	0,97 %	1.5%

* milk powder, butter and cheese

- EU milk and milk products imports (source TRACES)

Origin country / Year / Quantity (kg)	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
New Zealand	95108490	80129396	75292875	61587614	50565513	50893373
United States	3434991	33926500	19124228	3047930	9002031	45916436
Croatia	6863128	30169565	12702743	19507523	7146446	9488242
Australia	6875292	11623617	8885125	3742873	5616374	5304817
Israel	620006	1068296	1328196	2112820	717722	1077929
Iceland	20057	302149	869784	425009	192319	712893
Canada	4652339	5784890	6751666	3183618	1044195	72218
Argentina	31745	15588	15657	46744	21202	40138
FYROM	1129424	748770	2679875	365504	3234	8104
TOTAL	**118735472**	**163768771**	**127650149**	**94019635**	**74309036**	**113514150**

ANNEX IX: IMPACT IN THE EU AND THIRD COUNTRIES OF THE EU MEASURES ON ANIMAL CLONING FOR FOOD PRODUCTION – EFFECTS ON SECTOR COMPETITIVENESS

I. Introduction

1 Context

In the context of the identification of economic impacts of this initiative[144], particular attention has been paid to factors determining productivity and subsequently to the competitiveness of EU economic sectors involved. In this respect, competitiveness is defined as a measure of an economy's ability to provide its population with high and rising standards of living and high rates of employment on a sustainable basis. To deliver on these objectives, competition in a supportive business environment is a key to promote growth and competitiveness of sectors.

The EU sectors which would be potentially affected by measures on cloning are the animal farming sector (meat and milk production), the animal breeding sector (production of high genetic value reproductive material) and the food and retail industry (meat and milk production, processed foods, food imports, distribution and retail).

This analysis of impacts on competitiveness ('competitiveness proofing')[145] is performed through an assessment of the impacts on (i) costs and prices, (ii) innovation implications and (iii) the international competitiveness of the sectors involved. It is mainly qualitative, working with assumptions and draws mainly on studies prepared by an external consultant (GHK IFC 2012)[146] and the Commission's own Joint Research Centre (JRC Seville 2013).[147] However, the JRC study assumes that a "mandatory traceability and labelling system for food coming from offspring of cloned animals can be established in third countries" and that "the existing traceability system in third countries can be applied for the cloning technique without extra costs[148]". It will centre on the two main regulatory approaches (a) the suspension approach and (b) the traceability and labelling approach.

[144] This annex has been elaborated based on available data and information (see list of references). It reflects the policy options as identified in the IA report, except where otherwise stated.

[145] European Commission 2012: 'A "Competitiveness Proofing" Toolkit for use in Impact Assessments', Commission Staff Working document SEC(2012) 91 final

[146] IFC GHK 2012: "Impact in the EU and third countries of EU measures on animal cloning for food production", Final report to DG SANCO, 6 December 2012.

[147] JRC 2013: "Contribution to the economic impact assessment of policy options to regulate animal cloning for food production with an economic simulation model", JRC Scientific and Policy Report, EUR 25856 JRC 79995

[148] This assumption is however in contradiction with the third countries joint statement and no data on costs for third countries are available.

Taking into account that productivity increases resulting from use of cloning technique are marginal, it is assumed that cloning technique and cloned animals will not be used in the EU for food production up to 2020. Until then exposure of affected sectors in the EU is likely to be indirect, i.e. via the imports of reproductive material from clones, of live offspring and the food derived.

2 Background

The animal breeding sector aims at improving of genetic characteristics to increase production (e.g. of meat or milk). Breeding may indirectly affect production costs, notably feeding costs. Improvements resulting in better feed conversion rates (unit of feed/ unit of weight gained) are thus considered a major breeding progress as they have direct effect on the economic performance of the livestock farming sector.

The price of breeding stock (i.e. animals used for the purpose of planned breeding) or for animals used for production has a rather low impact on total production costs. For instance, considering the costs of pig meat production in EU countries in 2007[149], it emerges that breeding, veterinary medicine and energy costs are only about 6% of the total production costs. Production costs are mainly due to feed costs (about 50%). The situation is similar in the EU27 beef sector where breeding costs are about 6% of the total cost of beef production. On the demand side, farmers' share of the end consumer meat price is about 25%[150].

Evidence indicates[151] that productivity increases resulting from use of cloning technique as currently performed are marginal. There is thus little economic incentive to use it. As a result it is presumed that the technique would not be used for food production in the EU up to 2020.

II. Competitiveness analysis

1. Cost competitiveness

Production costs are only one of the many factors determining the competitive strength of a sector. They are influenced by the price, quality and dependability of purchased inputs and determined by the costs of land, labour, capital, machinery and stock as well as fertiliser, seed and fodder prices in e.g. animal production chains. Also in international trade transportation and import levies may also be significant. These additional costs counterweigh the usually higher in production costs between EU MS and between EU MS and third counties.

a) Suspension of cloning technique in the EU, imports of live clones, their reproductive material and their food (suspension approach).

As explained above it is presumed that the technique would not be used for food production in the EU up to 2020. As a result the suspension of cloning technique in the EU is not expected to have direct effects on costs for farmers and breeders in the EU.

There is a contingent risk of cost created by the loss of access to imports of live animals, reproductive materials and food derived could increase input costs for EU food business

[149] DG SANCO 2009: 'Draft background paper – the EUs role in the Global Food Supply Chain', based on Dutch Agricultural Economics Research Institute (Hoste R. (2009): Environment and welfare melt Dutch cost advantage. Pig Progress Volume 25 nr 3) and CRPA (De Roest, K. Jongeneel, J. Dillen, K. Winsten, J. (2008): Cross compliance and competitiveness of the European Beef and Pig Sector. Research Center on Animal Production (CRPA))

[150] Von Thunen-Institut 2013.

[151] IFC GHK 2012

operators. This risk would, however, only materialise if third country trading partners would not segregate clones and their products from other animals. In return EU farmers (especially in the meat/dairy bovine and ovine sectors) could benefit from loss of competition from imports if exports from third countries to the EU are disrupted or lost.

EU breeders currently import significant amounts of reproductive material from third counties (US and Canada) which is worth 50 millions €. Thus suspension import of reproductive material from clones may have a significant impact on both the EU breeding and farming sectors if third countries are unwilling or unable to identify reproductive material from clones. In consequence imports of reproductive material would become difficult. This could affect EU farmers if they would lose access to imported high performance genetic resources on certain farmer largely depend (e.g. dairy farmer using the Holstein breed).

b) Traceability and labelling of food from clones, offspring and descendants (traceability and labelling approach)

The cost of labelling can be split into the cost for underlying traceability and the cost of marking the food for retail.

The compliance cost of marking is negligible. Cost for adaptation or redesign of product labels are modest: the average cost at company level for a small label change has been estimated at €2,000-4,000. A full label redesign has been estimated at €7,000-9,000 (or €9,000-13,000 in total). Most companies (~80 per cent) redesign their label every three years as a normal part of their business operation (EC 2008).

The compliance costs for the underlying traceability, i.e. identification of animals, of reproductive material and of derived food becomes more costly with every generation between the clone and the animal, reproductive material or food traded and the degree of integration of supply chains. Increase in cost depend also on the degree that animals are already individually identified. Bovine and equine animals are already individually identified. For caprine and ovine species this is, with some exceptions, the case. Porcine animals are raised and moved in distinct groups. Thus traceability requirements related only to animal cloning in the EU are expected to have in principle minimal direct effects on companies' cost competitiveness for bovine animals if number of concerned animals[152] remains small and no direct effects for the other species in food production in the business (as usual baseline to 2020).

Impacts on cost competitiveness may arise through trade losses where third countries cannot or will not meet import traceability requirements for food. This could raise input costs in the EU market. If all live animals or batches of live animals require identification as a clone, offspring or descendant, the effects on cost competitiveness could be more significant, particularly for operators working with animal species for which profit margins are particularly low (e.g. ovine and caprine animals).

Some of the negative impacts may be offset if imports are restricted from third countries due to lack of compliance with traceability requirements and thus, EU producers would benefit from the subsequent loss of competition.

[152] The assumption is that only animals which are derived from cloning (clones or offspring) and reproductive material from clones would be subject to additional traceability requirements and that no additional traceability requirement would apply to other animals and reproductive material.

2. Capacity to innovate

The options assessed have the potential to change genetic diversity in the EU through changing the EU breeding sector's access to genetics from elsewhere in the world. If, in extremis, trade in reproductive materials ceased then EU breeders in the dairy sector and elsewhere would need to develop alternative strategies for the same breeds or turn to other breeds. The EU would, in functional terms, be cut off from access to the global 'pool' of genetic resources.

a) Suspension approach

As explained above it is presumed that the technique would not be used for food production in the EU up to 2020. Elsewhere the use of the technique is restricted to a very small number of animals and is concentrated in a single species (bovine animals).

The EU's 'exposure to the impacts of cloning over that period are likely to be indirect, mediated though use by operators in the EU of genetic materials brought in from North America. The net innovation impacts of the approach on cloning research and innovation are expected to be small in the short term. Stakeholder input suggests that EU industry would not invest in cloning for food production if unrestricted.

Suspension could have longer and indirect effects on the allocation of innovation investments in industry and upstream research funding by signalling explicitly that market prospects for the technology are not positive in the EU. Organisations looking to invest in the development of such technologies may be more inclined to place their investments elsewhere.

This may give rise to a competitive disadvantage for EU breeding companies on the long term. However, alternative approaches to cloning, in particular genomic selection[153] have been developed in the EU and their potential appears higher than that of cloning for livestock genetic improvement.

b) Traceability and labelling approach

Commercial cloning is unlikely to occur in the EU to 2020, the introduction of traceability requirements for reproductive material from clones is not expected to alter this.

There is no direct link between this approach and the capacity to innovate in the breeding sector but an indirect link as the additional costs for ensuring traceability and labelling of concerned animals and the lack of market in the EU for their food could decrease the interest for the technique.

3. International competitiveness

a) Suspension approach

The potential impacts of the suspension approach on international competitiveness are mixed and complex. The EU is not only the biggest importer but also a major exporter of reproductive material (semen, embryos). European breeding organisations are competitive on the global market for high value genetics that depends on continuous exchanges. Measures that hamper import or export of genetic material would weaken the position of the EU breeding sector in this global business.

[153] Genomic selection is based on detection at embryo level of the genetic potential of animals. This technology saves much time and resources compared to classical selection based on testing of adult animal performances for meat or milk production.

Table 1 summarizes the impacts of suspension approach on both import and export sides.

Suspension approach: effects on the import side	Suspension approach: effects on the export side
• An interruption of imports would reduce the exposure of domestic producers to competition in the EU market and would be expected to increase their relative competitiveness / market share. This could result in EU market share in third countries declining as a larger part of domestic output is absorbed by domestic demand. For example, bovine semen that the EU currently exports might be used for domestic production and North America would be likely to replace the EU in its current markets (typically South America) • A loss of access to high quality genetic materials could have long term impacts on output and on productivity, both of which could negatively impact on competitiveness in price-sensitive export markets	• Possible positive impacts on demand for EU products in third countries if the 'clone free' status was perceived as a premium attribute by consumers. • The acceptability of meat from clones, clone offspring and clone descendants for different religious faiths could also be relevant to the market prospects for EU products in such circumstances

There is thus some uncertainty about the scale and direction of the net effect on the EU's international competitiveness. However, it must be noted that the potential reduction of international competitiveness through loss of market access due to retaliatory trade measures introduced by third countries is out of the scope of this analysis.

A quantification of the likely effects of the suspension approach on international trade and EU domestic production has been attempted in a recent study by Commission Joint Research Center (JRC).[154] Among the various scenarios which have been used as a model for analysis by JRC, a scenario[155] considers that the cloning technique is suspended in the EU but remains available in third country main trading partners[156] which signed the joint statement on animal cloning for livestock production (Argentina, Brazil, New Zealand and the USA).

Under these assumptions no trade restrictions exist and the only difference between EU and Third countries lies in the productivity increase associated with cloning. The results show that imports would increase slightly in the case of a suspension of cloning in the EU but at the same time allowing the imports of food stemming from cloning. The EU would import marginally more cattle, beef and dairy, but the effects on prices and domestic production are negligible as imports represent only a small part of domestic use. This indicates that the productivity increase from cloning is not significant enough to change trade patterns.

Trade-mediated effects resulting from third country unwillingness or inability to comply with the requirements may negatively impact innovation, particularly for the bovine breeding

[154] JRC 2013: In the study the choice was made to perform the analysis through the use of a computable general equilibrium model called GLOBE. The different model scenarios are constructed based on combinations of the identified policy options such as suspension; traceability and labelling requirements with the productivity increase associated with cloning.

[155] Scenario 3 of 2013 JRC study.

[156] Most of them signed the joint statement on animal cloning for livestock production (Argentina, Brazil, New Zealand and the USA).

industry which relies on imported reproductive material to improve the quality of the breeding stock.

b) Traceability and labelling approach

The potential impacts of the traceability and labelling approach on international competitiveness have been assessed in the 2013 JRC study mentioned above. Some of the relevant impacts are reported in Table 2 below.

Table 2: Traceability approach - impacts on international competitiveness

negative impacts	**positive impacts**
Negative impacts in the case of fully comprehensive traceability for porcine, ovine, caprine and equine animal industries, due to significantly higher costs to operators (particularly breeders/farmers) in industries that already have low profit margins. This is particularly likely for pork products (batch traceability), for which the EU is a net exporter. No third country has such traceability requirements in place resulting in an advantage over EU operators in trade with other third countries. For domestic consumption, if the requirement is put in place for all third countries as well, then the overall competitiveness effect will be determined by the ease with which EU operators can comply with the requirements versus their competitors in third countries.	Traceability could have positive impacts on demand for EU products where it allowed operators to identify their products as 'clone free' and where this is perceived as a premium attribute by consumers. The extent to which this characteristic may be desired by consumers in third country markets is unknown.

The traceability and labelling approach poses the risk of triggering significant impacts on importers of food products and on the EU food supply chain due to changes in trade patterns. When food business operators from third countries cannot identify food products as derived from the offspring or descendants of clones and cannot satisfy the EU's import conditions for traceability, a compulsory product labelling scheme might drive EU buyers to seek alternative supplies. This would result in changes in the distribution of demand across the supply chain with EU buyers sourcing rather from EU producers/farmers.

The significance of major impacts for the three affected sectors in the context of the scenario 'suspension of imports of clones and meat from clones' and the scenario 'traceability and labelling of meat from clones and offspring' is summarised in table 3 below:

Table 3: Significance of the impacts of the two scenarios on the four main actors in the food chain

Actors	Suspension of imports of clones and meat from clones	Traceability and Labeling of meat from clones and offspring
Farmers	No impact on direct cost competitiveness; in the long term, there might be a potential contingent risk of loss of access to imports of live animals and especially reproductive material. Due to the fact that it is not conceivable how large the share of cloned animal will be, and which species will be covered, this risk to innovation and competiveness is hard to estimate but likely to remain limited. Benefits (limited) due to import substitution (price increases for producers)	Only minimal direct cost impacts for bovines; EU domestic farmers/producers will increase their market shares on the EU Single market due to slightly increased production which substitutes for decreased imports (notably from US beef and New Zealand sheep meat)
Traders	No imports of all meat types from clones, which are expected to be very limited in the first place Similarly, decreasing exports as meat demand on EU domestic market increase	For live animal imports, no significant additional costs (except USA*) due to requirements for individual animal identification For meat importers, significant additional traceability/labeling costs due to segregation of supply chains For EU exporters, potential comparative advantage on specific export markets of 'clone free' meat
FBO	No impact on direct cost competitiveness but in the long term potentially increased cost for private compliance mechanisms to ensure clone-free status Higher meat prices due to lack of imports and only partly substitution by domestic production (depending on species) notably for the meat processing industry	Significance of the impact on costs depending on (1) existing traceability system according to species; (2) establishment of segregated supply chains and (3) details of labeling rules including the FBOs possibility for integration into Business-as-usual costs

* Individual animal identification system exists in most of the major exporting countries with the exception of the USA.

In the absence of data on the shares that Member States have on EU imports, the significance of impacts by Member State, in order to determine which would be most affected, cannot be made. However, in order to provide best possible estimates, four factors can be considered:

1) The importance of animal production: For example, 60% of EU total production of dairy and beef originate from four countries (France, German, Italy and UK) while in sheep and goats, biggest producers in numbers are Greece, Bulgaria, Spain and Cyprus, with UK and Ireland also significant producers. It can be assumed, that the potential impacts of lack of access to genetic resources from third countries is more significant in these Member States.
2) The importance of the use of reproductive materials potentially from clones: This remains highly hypothetical for the time being. It is obvious that global breeding efforts will require continuous exchange of high-quality reproductive materials, especially for high-output species. At the same time, as the example of the World Holstein-Friesian Association (see

annex XIII) demonstrates, these sectors are already putting appropriate traceability systems in place on a voluntary basis.

3) On-going cloning activities in the EU: Of the 35 companies undertaking cloning activity worldwide, only four are active in the EU, and their commercial activities in Europe may not include the cloning technique.[157] Only France reported currently on-going cloning activities, but limited to sport horses. In Germany, in the past, clones were kept in semen centres but only for exports to third countries, not for distribution or use in the EU. Therefore, this factor currently has no impact on Member States at all.

4) Imports of meat and dairy into the EU: For the main imports (beef meat from South America, sheep meat from Australia and New-Zealand), specific impacts on Member States- are difficult to assess once products have been introduced into the internal market. For detailed trade numbers see annex VIII. However, imports decrease should be limited to a few products and remain rather insignificant as it would be at least partly substituted.

A summary of the impacts on competitiveness of the suspension approach and the traceability and labelling approach on the various affected EU sectors in presented in tables 4 and 5 below.

[157] Suk et al. (2007). Dolly for dinner? Assessing commercial and regulatory trends in cloned livestock. Nature Biotechnology, 25(1):47-53.

Table 4 Suspension approach (cloning technique, live clones, reproductive material from clones, food from clones)

Assumptions: 1) Suspension approach would reduce or cut access to genetic resources from third countries
2) Cloning technique would remain considered an efficient technique for improving livestock production.

Competitiveness / Sectors	Breeders / importers of RM	Farmers	Food industry and distribution/retail
cost and price competitiveness	No impact Cloning technique unlikely to be used in the EU for food production up to 2020.	Negative impact Short term: insignificant as technique is not widely spread yet and imports represent only a small part of domestic use long term: significant if performance cannot be increased though other techniques	short term: No impact as technique is not used in EU and not widely spread in third countries long term: increased costs through non availability of imports of cheaper conventional global market in food of animal origin yet effects on prices are negligible as imports represent only a
capacity to innovate	Negative impact Direct: EU breeders cut off global gene pool Indirect: allocation investments in breeding industry and upstream research => investments elsewhere	Negative impact If access to high performance reproductive material is disrupted or stoppedd	No impact Not the way food industry innovates
international competitiveness	Negative impact Loss of market share in the global market in reproductive material	- No access to high quality reproductive materials => long term impacts on output/productivity - May be outbalanced by gain in special/niche market	short term: No impact long term: increased costs through non availability of imports of cheaper conventional food of animal origin from global market.

Table 5 Labelling and traceability approach (traceability of live clones, reproductive material from clones, live offspring; food from clones and offspring).

Assumptions:
1) Labelling of food from clones and offspring can be put in place on the EU based on existing identification and traceability systems for live animals and reproductive material and possible adaption of food industry for traceability and labelling of fresh meat / food from offspring.
2) Most third countries would be unable or unwilling to put in place similar identification and traceability systems.

Competitiveness / Sectors	**Breeders / importers of RM**	**Farmers**	**Food industry and distribution/retail**
cost competitiveness	No impact	increase in compliance costs due to more detailed identification of animals increase depends on • degree of identification already established for species) number of generations to be identified	increase in compliance costs 1. marking of food: negligible if incorporated into 'label lifecycle' 2. traceability (identification of food through the food chain): potentially significant and increasing with: • length of food chain • complexity of food chain number of generations of animals to be identified • raise input costs as of cheaper conventional global market in food of animal origin not available
capacity to innovate	No impact	May trigger development of new more efficient ways to identify animals	May trigger development of new more efficient ways to ensure traceability

Competitiveness / Sectors	Breeders / importers of RM	Farmers	Food industry and distribution/retail
international competitiveness	Loss of share of global market in reproductive material + An interruption of imports would reduce the exposure of domestic producers to competition in the EU market and would be expected to increase their relative competitiveness / market share. This could result in EU market share in third countries declining as a larger part of domestic output is absorbed by domestic demand. For example, bovine semen that the EU currently exports might be used for domestic production and North America would be likely to replace the EU in its current markets (typically South America)	Loss of share of conventional global market in food of animal origin May be outbalance by gain in special market and loss of competition in Internal Market	short term: no impact long term: - increased cost through non availability of imports of cheaper conventional global market in food of animal origin - positive impact if EU clone free' products are premium attribute in TCs

III Combined scenario from JRC study.

Another scenario[158] analysed by JRC study is to combine the suspension approach and the traceability and labelling approach (suspension of cloning technique in the EU + mandatory traceability and labelling of food from clones and offspring). In particular, this scenario implies that the cloning technique is forbidden in the EU and remains available and used in third countries which signed the joint statement on animal cloning for livestock production (Argentina, Brazil, New Zealand and the USA). In addition, a mandatory traceability and labelling system for food coming from clones and offspring is established.

The following matrix **(Table 6)** aims to present the results of the qualitative screening for the JRC combined scenario.

Competitive losses	**Affected sectors**		**Sizing of impacts (significance)**	**Duration of impact**	**Risks and uncertainty**
	Directly	**Indirectly**			
Cost and price competitiveness	Domestic EU market: Live animal importers, Importers of RM, Breeders, Food importers, processors, manufacturers, retailers	EU exporters, consumer price increase	Indirect effects may be greater than the direct effects, particularly where trade losses occur due to third countries not being able or willing to meet traceability requirements	Short/long term	Risk of loss of access to imports of live animals and RM Potential trade losses where third countries do not meet traceability requirements to allow importers to meet requirements of suspension or traceability approach in the EU Risk of widely distributed negative impacts due to loss of imports
Capacity to innovate	Breeding industry, particularly bovines	EU exporters, research linked to reproduction and cell biology	Insignificant and small short term impact. Significant impact in the long horizon	Long term	Risk of inhibition of the EU's capacity to innovate in cloning

[158] Scenario 4 of 2013 JRC study.

International competitiveness	Domestic EU market: Live animal importers, Importers of RM, Breeders, Food importers, processors, manufacturers, retailers . In particular some benefits for EU domestic producers	Employment impacts for FBO, consumer price increase	Negative impact on competitiveness in price-sensitive export markets especially over the longer term	Short/long term	The additional administrative burden imposed on the food chain would be expected to reduce the competitiveness of the affected sectors

Note: RM stands for reproductive materials, FBO stands for Food Business Operators

Under this scenario, imports increase slightly when the EU decides not to use cloning but to allow the imports stemming from cloning. At the same time, the additional costs of setting up traceability systems in third countries would reduce the imports compared to the baseline for imports of primary products.

Concerning changes in the EU's domestic production, no significant differences to the baseline scenario are observed. This is expected as the changes in imports were marginal under this scenario and the competitive position of different sectors in the EU remains stable as the cloning technique cannot be used by EU farmers. Similarly, changes in import flows from main trading partners remain insignificant.

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ANNEX X: SME TEST

I. SME in the Food chain

SMEs play a key role in the EU food sector, at every stage of the supply chain. They represent nearly EUR 452 billion of turn-over, with EUR 93 billion of value added and employ about 2.7 million people in 271,000 enterprises which are 99.1% of total Food & Drink companies, and 48.7% of total turnover. [1]

The EU definition of small and medium-sized and micro enterprises[2]:

Enterprise Category	Headcount	Turnover	or Balance sheet total
Medium sized	< 250	≤ € 50 million	≤ € 43 million
Small	< 50	≤ € 10 million	≤ € 10 million
Micro	< 10	≤ € 2 million	≤ € 2 million

With a view to the main drivers in producing and marketing clones for food, 3 types of actors mainly composed of SMEs can be identified:

- Breeding companies (private and public), including multiplier organisations (breeding companies and farmers);
- Farmers/producers for meat and dairy;
- Food industry (processing).

1. Breeding sector

The breeding industry it is driven principally by SMEs. According to the European Forum of Farm Animal Breeders (EFFAB)[3], the livestock genetics industry mainly consists of SME and small units in larger organisations. The size of livestock breeding companies tends to be medium scale, with at most 2000 employees, and annual turnovers not exceeding €0.5 billion.[4]

The small number of players in the livestock breeding industry is the reflection of the specificities of the industry whereby genetic improvements brought about by breeding are cumulative (build on experience), permanent (no further breeding input is required once a superior animal has been bred), and can be rapidly disseminated to livestock farmers.[5]

Cloning and the advancements in cloning techniques is expected to accelerate and intensify the activities of the livestock genetics industry, especially with regards to delivering semen of top bulls and boars. In cattle, where artificial insemination (AI) can enable up to a million offspring, the economic prospects are seen as particularly promising, especially in comparison to pigs, where AI can produce around only 2000 offspring. [6]

[1] *Food Drink Europe: Data trends 2012*
[2] It is worth noting that this classification does not apply to the agriculture sector
[3] http://www.effab.org/
[4] Gura, 2007
[5] Simm et al. 1997
[6] Merks, 2006

Most multiplier organisations are SMEs cooperatively owned by farmers, operating in their native language, organised in national umbrella organisations. These national or local organisations of farm owners are internationally co-ordinated by a small number of private, elite breeding companies and cooperatives.

2. Farmers/producers

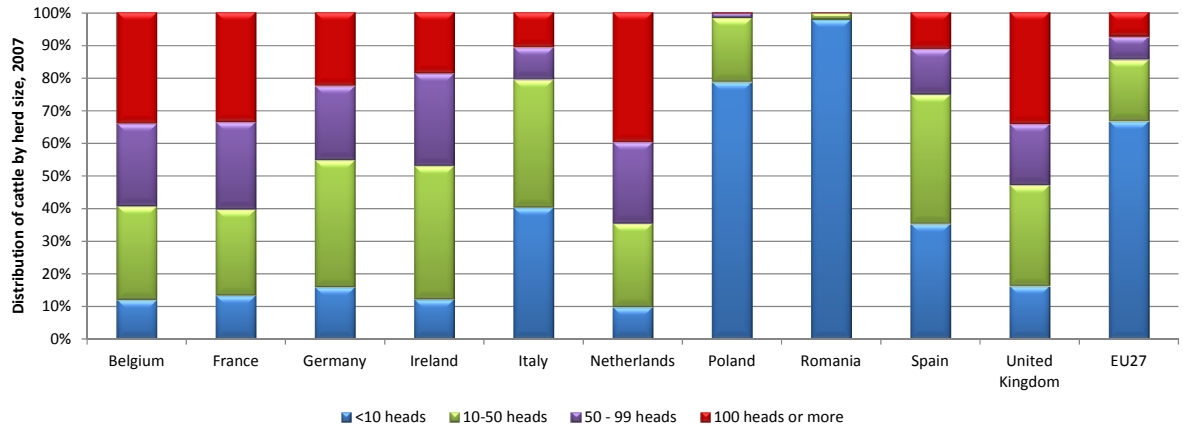
Holdings structure

In the EU Member States with the largest cattle and dairy cow populations, the majority of animals are kept on holdings with over 100 heads in size. In contrast, in the EU12 the majority of cattle and dairy cows are kept on small holdings of 9 animals or less.

The proportion of animals held on small holdings decreased while the number of animals held on large holdings increased. This trend occurred across the EU27 but was more pronounced in the new EU12.[1]

The production tends to be dominated by larger holdings in Northern Europe while the majority of cattle farms in Southern and Eastern Member States are smaller holdings of less than 50 heads.

Structure of the producers across the main EU countries



The distribution of cattle holdings follows a different pattern to the distribution of the cattle population. Over 50 per cent of European cattle holdings are located in Romania and Poland and only 34 per cent are located in the EU15. The majority of holdings (79%) in Poland (98%) and Romania are of between 1 – 9 heads.

By comparison, a large proportion of the holdings in Germany and France are of 50 heads or more (45 per cent and 60 per cent respectively). There are a larger number of dairy cow holdings in the new EU12, the majority of which are small holdings. [2]

3. Food sector

The Food sector is dominated by a large number of SMEs and micro-enterprises, which can be as high especially in the dairy products industry where 72% of all operators are micro-enterprises.

[1] GHK, 2012
[2] GHK, 2012
[3] IA OCR, 2012

For instance in Slovakia, only 13% of relevant enterprises are micro-enterprises and potential impact might be expected to be smaller, whereas in Sweden, the figure rises to 80% and potential impact would be expected to be much larger[3].

Micro Enterprises in meat sector

	Processing and preserving of meat and production of meat products			Manufacture of dairy products			Total		
	Total	**Micro**	**Share**	**Total**	**Micro**	**Share**	**Total**	**Micro**	**Share**
AT	1,092	763	70%	158	117	74%	**1,312**	**907**	**69%**
BE	823	571	69%	442	373	84%	**1,470**	**1,020**	**69%**
BG	475	201	42%	273	125	46%	**885**	**381**	**43%**
CY	71	46	65%	147	127	86%	**256**	**201**	**79%**
CZ	1,467*	:	:	146	:	:	**1,613**	**:**	**:**
DK	147	89	61%	75	49	65%	**408**	**232**	**57%**
EE	53	20	38%	31	11	35%	**156**	**63**	**40%**
FI	204	142	70%	52	29	56%	**480**	**355**	**74%**
FR	10,410 *	:	:	1,457	:	:	**12,363**	**:**	**:**
DE	11,044	6,558	59%	401	207	52%	**12,098**	**7,028**	**58%**
HU	592	334	56%	100	53	53%	**901**	**517**	**57%**
IE	133	26	20%	59	20	34%	**318**	**83**	**26%**
IT	3,559	2,495	70%	3,295	2,469	75%	**7,875**	**5,606**	**71%**
LV	128	62	48%	42	15	36%	**294**	**121**	**41%**
LT	176	69	39%	69	46	67%	**336**	**162**	**48%**
LU	27	14	52%	5	1	20%	**32**	**15**	**47%**
NL	491	325	66%	258	206	80%	**1,046**	**691**	**66%**
PL	3,283	2,134	65%	718	467	65%	**4,872**	**3,224**	**66%**
PT	633	382	60%	439	345	79%	**1,411**	**891**	**63%**
RO	909	532	59%	633	413	65%	**1,711**	**1,058**	**62%**
SK	72	17	24%	38	3	8%	**178**	**23**	**13%**
SI	163	110	67%	87	77	89%	**271**	**198**	**73%**
ES	4,153	2,771	67%	1,462	1,168	80%	**7,141**	**4,295**	**60%**
SE	494	367	74%	127	108	85%	**935**	**746**	**80%**
UK	1,035	545	53%	543	357	66%	**2,347**	**1,354**	**58%**
Total	**29,757 ****	**18,573**	**62%**	**9,454* ***	**6,786**	**72%**	**60,709**	**29.171**	**48%**

Source: Eurostat.

The impact on the food sector and notably the many SME will mainly draw from any new rules on labelling. However, in considering the economic impacts that might occur due to changes to labelling rules it is important to understand that even in the absence of labelling legislation, pre-packed food (such as dairy products) would still be labelled. Therefore, whilst changes in food labelling legislation may mean some additional costs associated with including the information required, companies producing pre-packed foods will always have costs of labelling that are not due to legislative requirements.[1]

[1] IA FIC 2008

Food retailers are composed of large companies (distribution chains) and of SMES (butchers, independent food retailers, local markets).

Food retail markets in the EU are increasingly concentrated with the market share of the top 3 retailers ranging from 30% to 50% in most MS, sometimes reaching between 70-90% (Ireland, Sweden, Finland and Denmark). In addition, this market concentration drives private label penetration, which has reached almost 35% in Germany and almost 40% in the UK (2010).[1]

The impact of new traceability and labelling rules for food would be very limited for these distribution chains: they have already put in place traceability systems for meat products for their own processing activities and would require their food suppliers to put in place all relevant traceability and labelling measures.

The impact would be considerably higher for independent retailers, butchers, local markets in terms of additional costs and administrative burden which could have significant impact on their business operations.

II. Impacts on SMEs

1 Suspension approach

The **suspension approach**[2] cannot provide an exclusion from the suspension requirements for SME businesses, from the farming sector through to manufacturing and retail. The approach therefore has the potential to impact on SME growth.

The expected impacts on SMEs mirror the expected impacts on EU businesses as a whole, but would be limited to impacts of live clones and their food which will be suspended. Trade-mediated impacts therefore dominate. Expected impacts on the farming sector (which has a high concentration of SMEs) are mixed: the number of imported live animals as low but with the potential for higher prices as the market seeks to compensate for the loss of high yielding animals. This in turn might have short run impacts on breeding plans for some businesses and the potential for longer run impacts on productivity growth for the sector as a whole.

Expected scale, distribution and type of impact on SMEs- suspension approach

Sectors where impacts will be concentrated	**Principal impact expected**	**Significance**
Live animal imports	Risk of loss of market in live animal imports (clones)	High for affected businesses but aggregate value of the trade is small
Importers of reproductive materials (RMs)	No impact	
Breeders	No impact	
Dairy/beef farmers	Farmers need to find alternative RM suppliers to maintain output	High in Member States with high dependency on AI & imported RM
Food processing and retail	No access to food from clones	Low

[1] *Food Drink Europe 2012: Data and trends 2011*

[2] No use of cloning technique in the EU

2 Traceability and labelling approach

The traceability and labelling approach[1] does not foresee exclusion for SME businesses, from the farming sector through to manufacturing and retail, and the approach therefore has the potential to impact on SME profit margins and growth.

The impacts on SMEs will vary depending on the chosen path. If all operators are subject to the traceability requirements such that they must identify the clone status of all animals, reproductive materials and food products then SMEs will be affected similarly to all other EU operators.

The requirements are more likely to affect the profits of small producers because they do not benefit from efficient production systems and/or economies of scale enjoyed by larger firms.

There is also likely to be variance in these impacts among Member States. Some MS have a large number of small producers. For example, in Poland (one of the EU countries with the largest pig populations) more than 60 per cent of the pigs are kept on farms with fewer than 50 animals. In Germany, higher production costs are already expected to cause the exclusion from the market of a large proportion of farms with fewer than 200 sows in 2013.[2] Additional costs for traceability could aggravate this impact.

Expected scale, distribution and type of impact on SMEs – traceability approach for clones, food derived from clones and reproductive materials

Sectors where impacts will be concentrated	**Principal impact expected**	**Significance**
Live animal importers	Aggregate value of the trade is small Few businesses likely to rely on trade in live animals to the EU Animals are high-value and therefore likely to be traceable with modest effort	Low High in Member States with high dependency on AI & imported RM
Importers of reproductive materials (RMs)	Materials are already traceable and identifiable in the major exporting countries as derived from a clone Risk of loss of access to imported reproductive materials leads to loss of business for importers where exporters cannot or will not identify reproductive materials from offspring of clones	Low High
Breeders	Loss of access to high quality Holstein/other genetics would negatively affects breeding programmes if RM importers halted	High in Member States with high dependency on AI & imported RM
Dairy/beef farmers	Farmers need to find alternative RM suppliers to maintain output	High in Member States with high dependency on AI & imported RM
Food importers, processors, food manufacturers, retailers and food service companies	Risk that import trades would be affected because exporters are unwilling or unable to meet the requirements on food products, but a supply chain solution to exclude clones from food suppliers seems more likely than a solution for clone offspring and descendants, which are more numerous and not traced	Low

[1] Imports of clone from TC allowed only if full traceability is provided

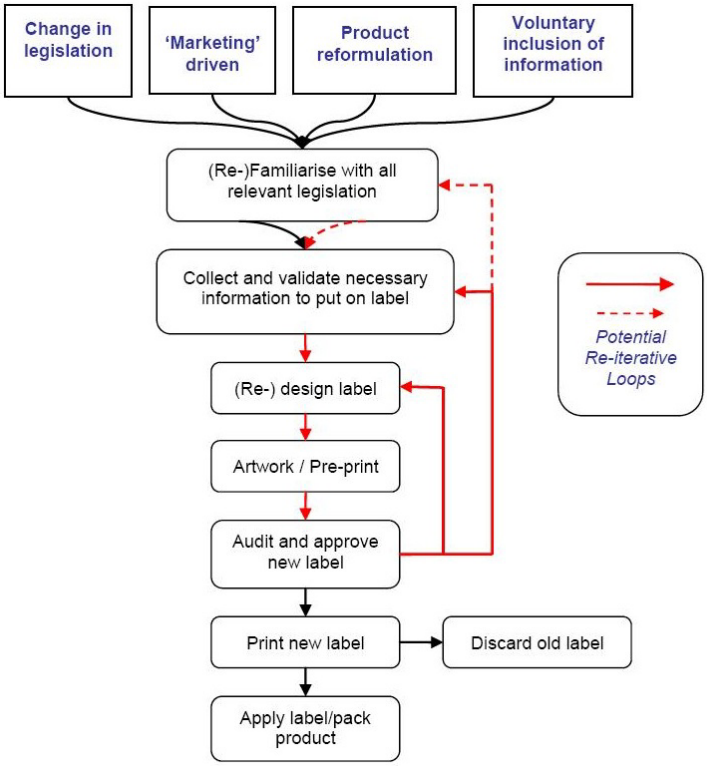
[2] http://www.thepigsite.com/reports/?category=903&id=903

Labelling mainly affects the food business operators (EU food industry, food importers, food distributors and retailers) which will have to comply with new labelling requirements.

The first impact of labelling results primarily from the setting up of new traceability systems or the upgrading of existing ones in order to ensure that labelling requirements are properly implemented. This has been assessed in the previous chapter.

The second impact of new labelling requirements result from the adaptation of the labels and labelling equipment and the need to replace the existing stocks of labels by new ones (see scheme below)[1].

Labelling process:



The evidence suggests that a move towards a mandatory labelling approach could present particular challenges for micro and small enterprises. This is because larger firms enjoy economies of scale, which lowers the cost per-unit of complying with regulations.
The changes in food labelling legislation may mean some additional costs associated with including the information required, companies producing pre-packed foods will always have costs of labelling that are not due to legislative requirements (for example printing and packaging costs).

A label change can be triggered by various reasons; the most common ones are: changes in regulations, marketing reasons and the producers usually change them at regular intervals.
This label's life cycles may range from a few months for highly marketed, or it might take a few years for niche products. Before designing/redesigning a label the company needs to be familiar with the legislation to identify the legal requirements for the new label.

[1] Defra May 2010, "Developing a Framework for Assessing the Costs of Labelling Changes in the UK", Report

For instance, in the light of an administrative burden exercise UK estimated the costs attributed to familiarisation and understanding the General Food Labelling regulations as 13% of all administrative costs across all the food regulations.
An administrative measurement exercise conducted in Denmark estimates the costs associated with familiarisation with food labelling legislation to account for 5% of the total administrative burden associated with the food regulations.[1]
However, the recent public consultation-based Communication on the ten most burdensome regulations for SME revealed that only 23 organisations mentioned the Food Information for Consumers (Regulation (EC) No 1169/2011).

In this context, it is relevant to point to the on-going exercise on a possible country of origin labelling (COOL) for meat and meat products as well as the revision of the Hygiene package, both of which are taking SME impacts specifically into account.[2]

III. Conclusions

A high level of protection of human life and health, as well as consumer protection, is the overarching objective of all DG SANCO policies and legislation (Art 169 TFEU).

The cross-cutting principles of promoting health, safety and the interests of European consumers are directly embedded in the Treaty. Therefore, as a matter of principle, all EU legislation regarding food safety and public health should apply to all business operators as their impact on the health and safety of citizens is highly significant.

The Commission is therefore cautious when considering any exemptions or lighter regimes for SMEs and micro-enterprises for these policy areas, since such exemptions should not undermine the high level of protection which has already been achieved.

Furthermore, the food safety requirements often bring positive, direct benefits to businesses - for example, a safe supply of raw materials for production, clear guidance to staff handling the production process, a high degree of consumer confidence and of our global partners and export markets.

In conclusion, it can be stated that the difference between SME and other FBO is not significant with reference to the factors subject to the preferred option.
This means, that although impacts can be identified, their impact is similar on all FBO regardless of size or turnover, while the overarching objective of the preferred option as outlined in the specific objectives of the IA can only be achieved if no exception is granted to SME.

[1] FSA (2006), "Food Standards Agency: Administrative Burdens Measurement Exercise: FinalReport", June 2006.
[2] http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2012_en.htm#SANCO

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ANNEX XI: ANALYSIS OF IMPACT ON TRADE IN CASE OF SUSPENSION OF CLONING TECHNIQUE

- *imports of (i) reproductive materials of clones, of (ii) life offspring & (iii) descendants* would continue to take place without restriction (eg subject to the relevant animal health and zoo-technical legislation applicable to all food and animals – see Summary of legislation on animal health and import certificates.

- *imports of food from these animals (offspring and descendants of clones)* would not be recognised as such and continue to be subject to all the relevant food legislation without any change ;

The suspension of cloning in the EU together with the suspension of imports of clones and the food from clones has very limited impact on trade but the clones need to identified as such in those third countries where cloning takes place and their food from clones not be put on the food export market.

In addition *the possible number of imported* of *live clones* - although there are no official figures - should be extremely low if non-existent: imports of live animals overall is extremely low; and the purpose of using clones is to trade their reproductive material (which is not affected by this option) and not to trade the clones themselves; imported live animals require documentation of the pedigree information of the animal, to confirm it is a clone or not. This information should be relatively easy to confirm given the small number of operators producing clones in third countries and EU operators' awareness of the status of the imported animal[1]. Based on the information received from breeding association they would be imported as pure bred or breeding animals for which the parentage is obligatory[2].

- *imports of food from clones produced in third countries* The cost to exclude food from clones from EU imports should be minimal and be put against the very small number of clones, compared to the livestock in third countries, and the fact that clones are not produced for food production. The voluntary system in the USA for example enables the food producer to decide whether or not to put it in the food chain.

[1] GHK study table 7.2. page 52
[2] See Annex XI.

ANNEX XII: COMPARISON OF OPTIONS ON IMPACTS AND OF OPTIONS ACCORDING TO OBJECTIVES

1: COMPARISON OF OPTIONS ON IMPACTS

OPTIONS						Economic		Social	Consumers	
						EU	**Third country**	**EU Employment**	**Protection**	**Food prices**
Option 1 (No Policy Change): Pre-market approval + labelling of food from clones on case by case + Directive 98/58/EC on animal welfare.						**0**	**0**	**0**	+	**0**
Option 2 (Pre-market approval): food from offspring and descendants						- - -	- - -	- -	0	- -
Option 3 (Labelling of food)	**Sub-option 1**: Food from clones	Mandatory	Segregated	All food	Clones	**0**	0/-	**0**	+ +	**0**
	Sub-option 2 and 3: Food from offspring and descendants	**Sub-option 4:** Mandatory	Segregated	Meat	Offspring	- -	- - -	**0**	+ + +	**0/-**
					Descendants	- - -	- - -	**0**	+ + +	-
				Other food	Offspring	- -	- -	- -	+ + +	- -
					Descendants	- -	- -	- -	+ + +	- -
			Non Segregated	Meat	Offspring	- - -	- - -	**0/-**	+ + +	-
					Descendants	- - -	- - -	**0/-**	+ + +	-
				Other food	Offspring	- - -	- - -	- -	+ + +	-
					Descendants	- - -	- - -	- -	+ + +	-
		Sub-option 5: Voluntary	Segregated or non segregated**	All food	All	**0/+**	**0**	+	+	-
Option 4 (Suspension in EU)	Cloning technique					**0**	**0**	**0**	++	**0**
	Clones					**0**	**0**	**0**	++	**0**
	Reproductive materials of clones					- -	-	**0**	**0**	**0**
	Food from clones					**0**	**0/-**	**0**	++	**0**

++ strongly positive; + positive; - negative; - - strongly negative; 0 no impact.

* meat process product; milk and milk processed products, meat ingredients; milk ingredients.

** Not to be set up by regulatory measure but by the FBOs depending on their activity, facilities and traceability equipment.

2: COMPARISON OF OPTIONS ACCORDING TO OBJECTIVES

OPTIONS						Specific Objectives		
						Animal welfare	**Consumer Protection**	**Competitiveness farmers / breeders / FBO**
Option 1 (No Policy Change): PMA + labelling of food from clones on case by case + Directive 98/58/EC on animal welfare.						**+**	**+**	**0**
Option 2 (Pre-market approval): Food from offspring and descendants						**0**	**0/+**	**0**
Option 3 (Labelling of food)	**Sub-option 1:** Food from clones	Mandatory	Segregated	All food	Clones	**0**	++	**0**
	Sub-option 2 and 3: Food from offspring and descendants	**Sub-option 4:** Mandatory	Segregated**	Meat	Offspring	**0**	+++	-
					Descendants	**0**	+++	- -
				Other food**	Offspring	**0**	+++	- - -
					Descendants	**0**	+++	- - -
			Non Segregated**	Meat	Offspring	**0**	+++	- - -
					Descendants	**0**	+++	- - -
				Other food**	Offspring	**0**	+++	- - -
					Descendants	**0**	+++	- - -
		Sub-option 5 Voluntary	Segregated** or non segregated	All food	All food	**0**	+	**0**
Option 4 (Suspension in EU)	Cloning technique					+++	++	**0**
	Clones					+++	++	**0**
	Reproductive materials of clones					**0**	**0**	- -
	Food from clones					**0**	++	**0**

Magnitude of impact of the option to attain the objective: ++ strongly positive; + positive; - negative; - - strongly negative; 0 no impact.

* Milk, meat and milk processed products, meat and milk ingredients.

** Not to be set up by regulatory measure but by the FBOs depending on their activity, facilities and traceability equipment.

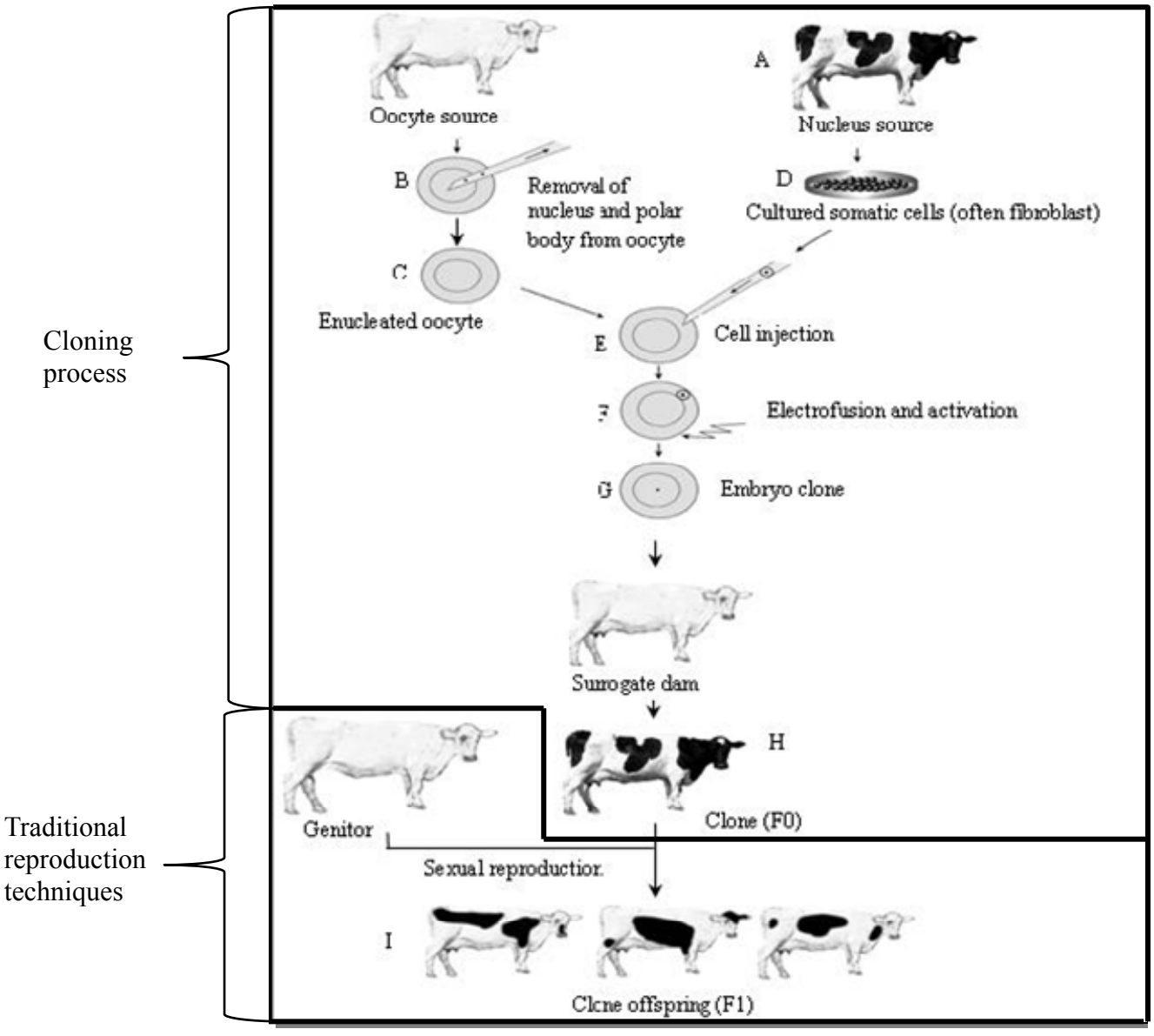
ANNEX XIII: BASELINE SCENARIO (BACKGROUND INFORMATION)

1. Technical Description of the Cloning Process

The animal cloning means an asexual reproduction technique of animals that involves the genetic material of one animal only (either a male or a female). This animal is called the donor and the technique aims at producing an almost exact genetic copy of the donor by using a surrogate mother. The technique does not involve any genetic modification.

More specifically, the technique consists (Figure 1) in taking the nucleus (which contains the genetic material DNA) of a cell of the donor and transferring this nucleus into an oocyte of a female. The original nucleus of the oocyte has been excluded. This implies that the genetic material of the oocyte has disappeared. The oocyte containing the transferred nucleus therefore bears only the genetic material of the donor. This new cell if successful develops into an embryo, which is then implanted into a surrogate mother. The surrogate mother - if the embryo develops properly - gives birth to the clone.

Figure 1 Process on animal cloning SNCT technique (Somatic Nuclear Cell Transfer-EFSA 2008 Scientific opinion)



This technique is rather complicated having for the moment a high rate of failures and it is therefore very expensive. At this moment the main species which are cloned for food production are bovine and pigs.

2. Price of Cloning, Cloning Activity Projected to 2020 and simulation of the number of offspring and descendants

a. Costs of cloned animals

Taking into account that no cloning activity is taking place in the EU (See 1.2.1 above) it can be estimated that the economic viability of cloning depends mainly on the cost of a clone and the pregnancy rate: The higher the costs, the more likely the use of cloning remains restricted to long-use high output animals (dairy cows, race horses), the lower the costs, the more likely the use of offspring for short term use (e.g. beef production).

Currently, the cost to produce a clone in third countries is thought to be €12,000-15,000 (COPA-COGECA interview). These animals can sell for more than €50,000. Breeding auctions in the EU sell good quality heifers for between €1,500-1,800 and bulls for €8,000-12,000, placing clones well above the top end of the range. Auctions in the United States have reported sale prices for the embryos of cloned bovine animals at a competitive price (USD 10,000-20,000), similar to the price of a 'conventionally bred' high-value line.

Due to the high cost of cloning and low success rates from SCNT techniques, cloning is currently seen as potentially useful as 'insurance' whereby breeders may seek to protect themselves from the premature injury or death of highly valuable animals by creating and storing somatic cell lines of those animals. Clones of elite animals could thus be used as sires for multiplication of beef cattle and dairy cattle with desirable characteristics.

b. Projection of the use of cloning in the EU

Suk et al 2007 estimated that the offspring of cloned cattle would likely enter the food chain somewhere in the world before 2010. The industry's view at that time suggested that the estimated timeline for commercialisation of cloned animal food products was:

- 2005 – 2010: semen and offspring from cloned cattle and milk, meat and derivatives from offspring of cloned cattle.
- 2010 - 2015: cloned cattle and milk, beef and derivatives from cloned cattle would enter the food chain.

Offspring from cloned cattle did enter the food chain in the UK in 2010 through the slaughter of two sires for dairy cattle. No other such activity has been reported in the EU, although the EU does not currently regulate the import of reproductive material from clones. It is possible that additional offspring of clones have been produced elsewhere in the EU. No clones are known to have entered the food chain in Europe to date as no pre-market approval requests have been submitted under the Novel Foods Regulation.

c. Simulation of the potential number of offspring and descendants from a cloned bull

The exponential increase of the number of offspring and descendants happens for semen, ova and embryos. It is particularly important when semen is used in artificial insemination. The number of offspring from one single bull is in order of thousands in his entire lifetime. In the case of elite bull the number of offspring (male and female) can be as high as 5000 to 10000. In case of elite cows and after superovulation treatment for embryo transfer, the number of transferable embryos can be 50 embryos in her entire lifetime. Like the artificial insemination has done for the bull, embryo transfer can greatly increase the number of offspring that an elite important cow can produce. Without this embryo transfer technology a cow will produce an average of 8 calves in her entire lifetime under normal management programs (See table 1 on the simulation of number of offspring and descendants).

Table 1 Simulation of number of offspring and descendants

	Offspring first generation (usually half female and half male)	**Descendants Second generation** (only female offspring*** used- and males sent to slaughtering)	**Descendants Third generation** (only female offspring*** used- and males sent to slaughtering)
Elite Bull *	5000- 10 000	20 000 - 40 000	80 000 - 160 000
	10 elite bulls from the 2500-5000 males	50000 -100 000	200 000 – 500 000
	10 elite cows from the 2500-5000 females	500	2000
TOTAL	**5000 – 10 000**	**70 500 -140 500**	**282 000 – 662 000**
Elite cow** (after superovulation treatment for embryo transfer)	50	200	800
	5 elite cows from the 25 females	250	1000
	1 elite bull from the 25 males	5000 – 10 000	20 000 – 40 000
TOTAL	**50**	**5450 -10 450**	**21 800 – 41 800**

Source Information provided by UNCEIA (French National Association of livestock & Artificial Insemination Cooperatives).

*An elite bull can produce in average between 5000 and 10000 offspring first generation (half male and half female).

**An elite cow can produce in average 50 offspring first generation (half male and half female).

***A cow will produce an average of 8 calves in her entire lifetime under normal management programs

3. Background Information on Cloning-Companies, Number of Clones in third countries and Supply Chain Management for clones in the US

a. Cloning companies

Based on the information gathered by the consultant GHK on companies' websites few companies carry out cloning only – most of them are also producers of other livestock reproductive material. The consultant did not succeed in getting any information directly from the cloning companies. The GHK study also reports that JRC study (2007)[177] found that of the 35 companies undertaking cloning activity worldwide, nine of these applied cloning technology to cattle. Four of these companies are represented in the EU, although their commercial activities in Europe are not thought to include use of the cloning technique.

Company Name	Head Office	# Employees	Revenue	Europe Offices	Presence in key third countries
AltaGenetics	Canada	Canada: 5-10 US: 50-100	Canada: $500,000 US: $10-$25m	NL	Uruguay, Argentina, Chile, US
Celentis	NZ	Celentis: 50-100 AgResearch: 780	Celentis: $10-$25m AgResearch: 157.7m		
Cyagara/ Goyaike*	US	1001-5000			Brazil, Argentina
Genus/ Bovec/ ABS	UK	1000-5000	309.9m (Euro)	IT, DE, FR, IE	US, Canada, Brazil, Argentina, Australia, Chile
Minitube (Intl Centre for Biotechnology)	US	400+	US: $10-$25m		Asia, Australia, North American, South America
TransOva	US	50-100	$10-$25m		
Viagen	US	50-100	$1-$15m		
Yangling Keyuan cloning co.	China	50+	2-3m (RMB)		

Source: Cloning company websites

[177] Suk et al. (2007). Dolly for dinner? Assessing commercial and regulatory trends in cloned livestock. Nature Biotechnology, 25(1):47-53.

b. Number of clones in USA

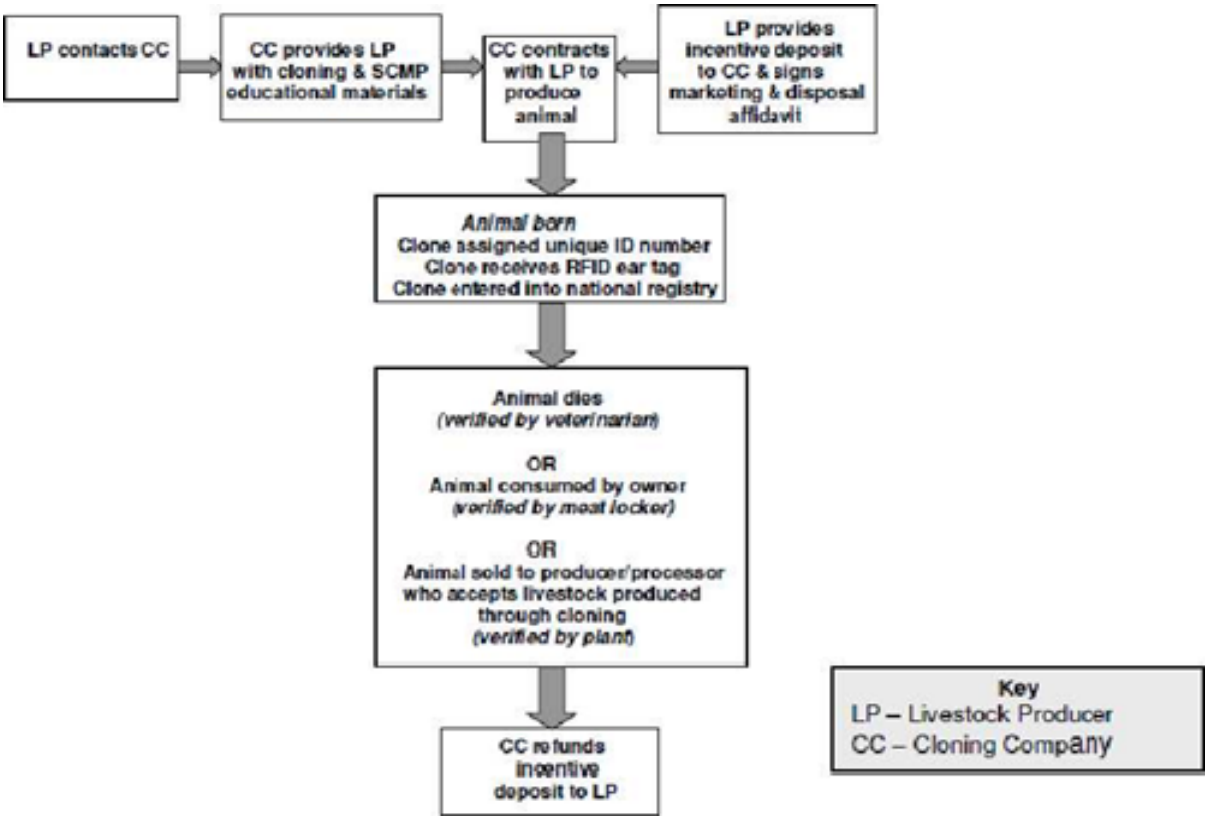
Information provided by USA cloning companies (TransOva and ViaGen) to DG SANCO on 9 December 2012 by teleconference.

Species	Number of clones in the USA	Success rate of cloning technique	Cost of a clone
Bovine	1100 (50% male and 50% female)	10 to 20% depending of races	18000$
Pigs	190	>50%	1500$ for each piglet (6 on average)
Horses	>100	15%	165000$
Sheep	0	--	--
Goats	At start	No information provided	No information provided

c. Supply Chain Management for Clones in the US

A paper-based supply chain management programme for verification of clones was set up in the US but has since been discontinued. It was implemented voluntarily in the US for clones (but not their offspring or descendants) and reached to the point of slaughter. The system was developed by the largest US livestock cloning companies, ViaGen and Trans Ova Genetics.
The Supply Chain Management Program (SCMP) involved a registry system that followed livestock clones from birth to death and carcass disposal. The key components of the program were education, a national clone registry, affidavits, and incentives (Figure 2).

Figure 2 US Livestock Cloning Supply Chain Management Program Overview
Source: http://www.clonesafety.com/documents/SCM_How.pdf



The Colorado based company, AgInfoLink, managed the database of animals identified with an Animal Identification Number. The system was designed to manage only cloned animals, not their offspring. Consultation with the cloning industry in the US indicates that the SCMP system was operational for five years but that it was discontinued because there was no demand for it, neither from consumers nor from companies. No claims for labelling of cloned pedigrees were submitted.

The program functioned as follows:
■ Cloning company contracts to produce animal following owner education.
■ Owner signs an affidavit committing to proper marketing or disposal of animal or milk products.
■ Owners get refunded an incentive deposit they had previously paid to the cloning company when they notify the company of animal death (verified by a veterinarian), consumption by owner (verified by the meat locker) or sale to a packer/processor who accepts livestock produced through cloning (verified by a signed statement from the packer/processor).
■ The incentive deposit was based on a value higher than market value for a similar animal.

4. Genetic Diversity

Regarding **genetic diversity**, the suspension of the cloning technique should have no major impact as the breeding sector has to pay much attention to avoid consanguinity and avoid having too many animals with the same genetics
Traditional breeding of farm animals already concentrate on the genetic improvement of specific traits (such as milk yield or meat production), which results in a reduction of animal species and a low range of breeds in particular in industrialised countries[178].

Cloning can be used commercially to duplicate elite breeding animals and therefore reduce the number of animals used in breeding programmes. This could contribute to the further loss of genetic diversity (EFSA, 2008). Breeding programmes utilising only a few bloodlines also may increase the susceptibility of an animal population to risk factors such as infection by disease and climate change (EFSA, 2008).
EFSA (2008) reports that, where used appropriately and with suitable management measures, these adverse effects can be avoided. While EFSA foresees no 'new or additional' environmental risks from cloning, the data are limited (2008). This was confirmed in the updated EFSA 2012 statement (EFSA, 2012).
In the dairy sector consanguinity could in the future become a serious problem[179] as a high output dairy cattle breeds like the Holstein account already for 75 per cent of the world's milk supply (FAO 2007)[180]. This situation is not necessarily linked to cloning but could be

[178] The impact of genetic selection for increased milk yield on the welfare of dairy cows. PA Oltenacu and DM Broom.
[179] The impact of genetic selection for increased milk yield on the welfare of dairy cows. PA Oltenacu and DM Broom
[180] FAO, 2007. 'The state of the World's Animal Genetic Resources for Food and Agriculture'

exacerbated if cloning is used widely in third countries and their reproductive material imported in the EU.

5. World Holstein Friesian Federation Guidelines for Registered Clones

1. International Embryo Transfer Society (IETS) forms (or forms with similar format and information) should be completed and submitted to appropriate breed association prior to, or with application for registration of a clone. The type of cloning technology should be provided by the company producing clones -- cells from an adult animal, a foetus; or an embryo.
2. A code or suffix should be used in the name or as a part of the record of identification. This code or suffix should show on certificates of registration, pedigrees, and all other official Association documents. NOTE: (Holstein Canada records the code "ETA" on the second line, under the name of an animal, on a certificate of registration if cells are from an adult animal or foetus, and uses ETN if cells are from an embryo. Holstein USA uses the suffix "ETN" in naming all clones.)
3. When a cloned calf is registered, the breeder of the entity from which the nuclear material originates should be recorded as the breeder and the breeder's prefix should be used in the name.
4. The name of each clone should be distinguished by an Arabic number starting with the digit 2 either preceding the suffix or at the end of the name. Cloned calves can be registered with the same name as the source animal followed by the appropriate Arabic number. The sire and dam of a clone should be the same as the sire and dam of the source animal, foetus or embryo.
5. The identification of the source animal should be recorded on the registering Association's records and associated with the registration record for the resulting clones. This information should be made available, if requested.
6. Each breed association should establish its own policy on the amount of parentage testing to be conducted, using either DNA genotyping or blood typing, but it is recommended that all clones be DNA genotyped or blood typed. The testing results must show that the source animal and clones have identical genotypes/blood types.
7. Each breed association should establish its own policy and procedure relating to the registration of progeny of a clone.
8. If cloned animals or embryos resulting from cloning are exported, the accompanying documents should provide all information required by the Association in the importing country.

WHFF-Council Recommendation (October 2006, Killarney, Ireland).