

EN

EN

EN



EUROPEAN COMMISSION

Brussels, 19.10.2010
COM(2010) 585 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

on animal cloning for food production

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT
AND THE COUNCIL**

on animal cloning for food production

TABLE OF CONTENTS

1.	INTRODUCTION.....	3
2.	ANIMAL WELFARE ISSUES.....	4
3.	ETHICS.....	5
4.	SITUATION IN THE MEMBER STATES.....	6
5.	SITUATION IN THIRD COUNTRIES.....	7
6.	PUBLIC PERCEPTION AND STAKEHOLDER OPINIONS.....	8
7.	TRADE ISSUES.....	9
8.	LEGAL ASPECTS TO BE TAKEN INTO ACCOUNT IN THE RISK MANAGEMENT.....	10
9.	OPTIONS.....	12
10.	CONCLUSIONS.....	14

1. INTRODUCTION

This report presents an assessment of cloning technology in relation to food production. The objective is to examine the relevant aspects of cloning in light of the current legislative framework.

Cloning¹ is a relatively new breeding technique which allows the asexual reproduction of animals that have shown good productivity, low incidence of disease and the capacity to cope with the production environment. The scope of the report is limited to animals when raised for food production. The animal which is obtained (the clone) is a near exact genetic copy of the original animal. As with any other breeding technique, it is important to undertake risk assessments on critical aspects in order to address possible risks as regards food safety and the health and welfare of animals. This report also examines other aspects, such as the ethical dimension, trade implications and the consumer's right to be informed about the production process.

An opinion of the European Food Safety Authority (EFSA) adopted on 15 July 2008², cited difficulties in relation to the risk assessment of cloning due to the limited number of available studies. It also noted that the health and welfare of a significant proportion of clones had been found to be adversely affected, often severely and with a fatal outcome. The opinion found no indication of any differences in food safety for the meat and milk of clones and their progeny compared with conventionally bred animals. Finally, the opinion did not envisage environmental impacts, but acknowledged the limited availability of data.

On 26 June 2009, EFSA published a statement on further advice on the use of animal cloning³. This statement confirmed the validity of the conclusions and recommendations of the 2008 EFSA opinion, adding that the main source of the adverse effects that may affect clones and result in developmental abnormalities was "epigenetic dysregulation"⁴. Failure of the placental development following cloning is believed to be one of the reasons why the technique has a low success rate. Adverse affects, however, vary between species. For example, large offspring syndrome (LOS) affects cattle but not pigs. This condition can result in difficult birth and health problems for the surrogate dams and cases of stillbirth. Neither of these phenomena appears to affect the offspring of clones, born through conventional breeding techniques.

The EFSA statement of 2009 also noted that if the success rate of the epigenetic reprogramming were to be improved it is likely that the incidence of pathologies and mortalities would decrease.

¹ For the purposes of this report (and in common with EFSA and EGE Opinions) "cloning" refers to replication by somatic cell nuclear transfer (SCNT) to create genetic replicas (clones) from adult animals that share the same nuclear gene set as another organism. This report does not cover embryo splitting or any form of genetic modification.

² http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902019540.htm

³ http://www.efsa.europa.eu/cs/BlobServer/Statm_of_Efsa/sc_statemetej_RN319_en.pdf?ssbinary=true

⁴ "Epigenetics" seeks to describe the inheritance of information on the basis of gene expression. Epigenetic changes in reprogramming of the donor's nucleus in SCNT have been implicated in causing many of the observed anomalies.

Japanese research institutes have been studying animal cloning since 1998. Living clones and their progeny provide important data allowing analysis of the health and welfare status of those animals. Between July 1998 and September 2009, 575 cloned cattle were born in Japan of which 55% died shortly after birth⁵.

In May 2010, the Commission asked EFSA for a further update of the scientific assessment of cloning: The EFSA statement of September 2010 indicated that:

"Being a genetic copy of its cell donor, the clone has similar potential productive performances. It should be stressed that besides quantitative/qualitative traits of animal products, today's selection strategies take into account other relevant parameters, including resistance to the common pathologies (e.g. mastitis, other infectious and parasitic diseases), fertility, mentality and others related to the general robustness of the animal. Breeding out such complex traits using the traditional selection schemes is time consuming and might turn out to be complicated and the success is not certain. Cloning could contribute to address these issues in a more rapid manner."

Concerning genetic diversity, the statement indicated that:

"An argument often voiced is that cloning will decrease genetic diversity. However, if used appropriately, in connection with suitable management measures, cloning is not expected to adversely affect the genetic diversity among domestic species."

2. ANIMAL WELFARE ISSUES

The available EFSA opinion associates animal welfare problems with the current state of the application of the cloning technique. Cloning presents severe welfare challenges for clones arising directly from its use and also through possible exacerbation of the problems caused by selective breeding.

First of all, as highlighted by EFSA, a large majority of cloned embryos fail to develop to term and, for those that do, a significant proportion of the animals die during or shortly after birth, or over the following days and weeks, from cardiovascular failure, respiratory problems, liver or kidney failure, immunodeficiencies or musculoskeletal abnormalities. Significantly, EFSA stresses that: *"the mortality rate of clones is considerably higher than in sexually produced animals"* and that there is *"evidence of increased morbidity of clones compared with sexually produced animals"*.

Based on the available data, the overall success rate of the cloning procedure (measured as the percentage of live clones born from the number of embryos transferred) is less than 10% in bovine animals and between 5 and 17% in pigs. Studies undertaken outside Europe have shown that the survival of the progeny of clones does not differ to any significant extent from the survival of conventionally bred animals (around 85%).

⁵ Dr. Shinya Watanabe, National Institute of Livestock and Grassland Science, Japan.

In its opinion, EFSA also highlighted important welfare issues for surrogate cattle dams which suffer from late gestational losses, more difficult delivery (dystocia) and large offspring. Additional welfare concerns are related to the fact that clones may be born unusually large and with a range of associated health problems, termed “large offspring syndrome” (LOS). This is a common problem in cattle and sheep clones, but not in pigs. It should be noted that some abnormalities may not show up until later in life. Writing in the *OIE Revue Scientifique et Technique* a leading cloning scientist pointed out that the development of musculoskeletal problems, such as chronic lameness and severely contracted flexor tendons, in these high-production animals “*emphasises the point that any underlying frailties in cloned animals may not be fully revealed until the animals are stressed in some manner.*”⁶

In order to correctly assess the impact of cloning on the welfare of farm animals, it is important to consider the ways in which cloning is likely to be used within the livestock sector. Whilst the cloning of the fastest growing and high yielding animals may lead to higher proportion of animals suffering from such health and welfare problems, the cloning of conventionally bred animals, which are resistant to certain diseases or which can easily adapt to difficult environmental conditions, may have some possible benefits from a welfare point of view.

3. ETHICS

The European Group on Ethics in Science and New Technologies (EGE) published a report on the ethical aspects of animal cloning for food production in January 2008⁷.

The EGE expressed doubts on the ethical justification of cloning animals for food production purposes, “*considering the current level of suffering and health problems of surrogate dams and animal clones*”. The EGE also concluded that the issue of ethical justification on the progeny of clones was open to further scientific research and did “*not see convincing arguments to justify the production of food from clones and their offspring*”.

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

Actions causing pain to moral subjects are considered morally problematic. Therefore, if cloning or any other breeding or farming technique affects animal welfare and health, then this use is difficult to accept. Such theories have advocated the possible use of animals only under specific conditions where animal pain is minimised and authorised in well-justified circumstances based on the 3Rs (reduction, refinement and replacement) principle and on the five freedoms as defined by the Farm Animal Welfare Council (FAWC): freedom from (1) hunger,

⁶ Wells DN. 2005. Animal cloning: problems and prospects. *Revue Scientifique et Technique* (International Office of Epizootics) 24(1):251-64.

⁷ http://ec.europa.eu/european_group_ethics/activities/docs/opinion23_en.pdf

thirst and malnutrition; (2) fear and distress; (3) physical and thermal discomfort; (4) pain, injury and disease; and (5) freedom to express normal patterns of behaviour.

Another theory defends an even stricter line, advocating that animals have a moral value in themselves as "subjects-of-life" (intrinsic value argument) and states that both human and non-human beings are (analogously) moral entities because of their sentient capacities. The corollary of this argument is not to use animals for human purposes. Therefore, there is opposition to animal bio-engineering on the basis of categorical arguments.

Another ethical issue concerns intellectual property rights. Patenting in animal cloning is so far limited to nuclear transfer techniques.

4. SITUATION IN THE MEMBER STATES

Imports, trade and use of products from clones (food, semen, and embryos) are covered by general EU legislation. There is no obligation for operators or authorities to notify the production, trade or import of clones or their semen and embryos so it is not possible to gain a complete picture of the overall situation. However, for meat and milk a pre-market authorisation is mandatory, according to the Novel Foods Regulation⁸.

Denmark has imposed a national ban on the use of animal cloning for commercial purposes. Any exemptions to this ban must be approved and must demonstrate a benefit taking into account the stress or suffering caused, including considerations of animal integrity, instincts and welfare. At the core of this ban lies the ethical concern that this might lead to human cloning, hence Denmark is in accordance with the 2005 United Nations Resolution calling on its Member States to "*prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life*".

Apart from Denmark, no other Member State has any specific legislation on the use of cloning. However, some have provisions in national animal welfare legislation on breeding and genetic engineering relating to possible pain and suffering of animals associated with reproduction techniques. In Denmark, the cloning of animals is permitted only if it serves an essential purpose. Examples of what is considered an essential purpose are basic research, applied research aimed at improving health and the environment or creation and breeding of animals producing substances essentially benefiting health and the environment.

The Commission has received detailed information from some Member States, which use cloning technology for research purposes only. The United Kingdom reported three cattle that are the progeny of clones imported as embryos. Germany reported cloned donor bulls, the semen of which has not yet been used within the EU but has already been exported to third countries. France reported that since 1998 a total of 90 bovines have been born by cloning at the Institut National de Recherche Agronomique (INRA). Currently there are 32 living cloned cows. These animals are

⁸ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

used only for research purposes and are slaughtered, as are their descendents, as soon as their research use has ended. Their products are not used as food. In addition, 30 offspring of bovine clones have been born by artificial insemination. Males were studied until the age of three months and then killed. Females are reared in order to undertake studies. Currently INRA keeps sixteen young females, offspring from clones, in the framework of a research programme.

5. SITUATION IN THIRD COUNTRIES

The USA is the most advanced country as regards the cloning of animals for food production. The situation is also evolving in other countries such as Argentina, Brazil and Japan. China has expressed interest in the technique and has imported clones from Australia amongst others. In addition to the Chinese focus on pets, China has also advocated the use of cloning for the preservation of endangered species.

A voluntary moratorium for the marketing of food products (meat and milk) from clones is in place in the USA. This moratorium does not, however, cover food from the offspring of clones nor semen and embryos from clones. Generally there is no specific labelling or monitoring of semen and embryos from clones and their offspring. Therefore, it is not possible to substantiate precise figures on the possible export of semen and embryos to the EU, as clone donors of semen are owned by farmers, and cloning companies do not have control over their use.

In the USA three major companies sell clones to farmers. Two of the companies put in place a voluntary tracking system, giving every clone a unique identification (ID). The system does not however extend to tracking the offspring of clones. The programme works through the use of a national registry, based on written statements of truth and incentives. The ID of the clone is entered into a registry that can be queried and verified by the livestock auction market or packer/processor. The US companies involved in cloning have contacted the Commission services several times in order to express their views. The relevant facts can be summarised as follows:

- Regarding the number of clones, the companies have not provided (for commercial or confidentiality reasons) precise figures but have often mentioned "hundreds of pigs" and "thousands of cattle". Therefore products of offspring of clones have entered the food chain, not only in the US but also in other parts of the world (not least in Brazil where there are five companies involved in cloning).
- Regarding traceability, clones are tracked through a registry, plus there is an economic incentive for farmers not to introduce clones into the food chain. However, this tracking is not mandatory, so it cannot be guaranteed that milk from clones does not enter the food chain (even if it is unlikely that such milk would be used for food purposes). Offspring from clones are not tracked.

In Japan, the National Research Institute assessed the use of cloning technology and concluded that the government would not take any regulatory measure (such as prior certification or labelling of imported food from clones and their offspring). However the current voluntary moratorium on the domestic production of food products from

clones and their offspring will be retained. Therefore semen of cloned bulls is collected and stored but not used for commercial purposes. Argentina reported that cloning is taking place for commercial purposes. It has no registry for clones. Brazil reported that cloning is only taking place for research and not food purposes. A draft text is being discussed in the Brazilian Senate and the Ministry of Agriculture is expected to present a proposal for the obligatory registration of animal clones in a national database. Canada requires pre-market approval on a case-by-case basis for food from clones. The current policy is being reviewed and the Canadian authorities are awaiting a scientific opinion on food safety and animal welfare, which is expected by the end of 2010. New Zealand has a moratorium establishing that clones cannot enter the food chain. In June 2010 the authorities introduced a national registry scheme for clones. An official traceability system will also apply.

Given the differences of approach with our international partners, there is scope to further deepen our understanding of the regulatory frameworks and research parameters that guide cloning outside the EU. To this end the Commission will strengthen the dialogue with trading partners in order to explore the possibility of finding common ground for an understanding on cloning.

6. PUBLIC PERCEPTION AND STAKEHOLDER OPINIONS

In 2008 the Commission launched an opinion poll⁹ (Eurobarometer) to assess public attitudes towards animal cloning. The study showed that a majority of EU citizens, whilst having an understanding of the concept of animal cloning, had a broadly negative perception of its use for food production. Many were concerned about the lack of information concerning the long-term consequences of cloning and many cited ethical concerns. There was a general feeling that the cloning of animals for food production purposes would not benefit the consumer, with few believing that using cloning for food production would be much more efficient in the long run or lower the cost of food products for consumers.

However, in contrast to the generally negative perception of cloning, 44% thought that cloning can be justified under certain circumstances, such as for the improvement of resistance of animals against diseases or to preserve rare animal species.

Animal welfare groups have campaigned strongly against the use of cloning for food production in the EU. These groups claim that animal welfare legislation, provides a basis for the prohibition of the technique to prevent detrimental effect to the welfare of the animals. The same animal welfare groups stress the need to apply restrictive measures to products from the offspring of clones, even if such animals are produced through conventional breeding techniques. They consider it essential for the offspring of clones to be included in the EU's approach to cloning for food. According to these organisations, a prohibition of the placing on the market of meat and milk from clones (but not their offspring) would not be enough to restrain the use of the technique in Europe.

⁹ European attitudes towards animal cloning: http://ec.europa.eu/public_opinion/flash/fl_238_en.pdf

While assessing the situation, the Commission discussed with the EU agri-food sector the use of cloning, taking into account the interests of the livestock sector with respect to access to this innovative technology. The Commission discussed with the Association of European farmers and of European agri-cooperatives (COPA-COGECA) the possibility of a voluntary moratorium for a limited period of time on the use of clones and their offspring. The purpose of such a voluntary moratorium would be to ensure that future regulatory options would not be compromised by the appearance on the EU market of such animals and animal products. However, COPA/COGECA¹⁰ takes the view that such a moratorium would not be appropriate, in particular because there are currently no means, nor controls, first to ensure full traceability of imported products and second to legally pursue those who break the moratorium.

The European meat processing industry CLITRAVI¹¹ states that products from cloned animals and/or their offspring thereof are being sold within the EU and that setting up a traceability system will be very costly.

Both Parliament and Council expect the Commission to work on a separate proposal on all aspects of cloning. In the Position adopted in March 2010 the Council extended the Novel Foods pre-market approval to food from the offspring (first generation) of clones¹². The Parliament reiterated, at its July plenary, its request for a total ban on the cloning of animals; on imports of live clones and their offspring; on the marketing of food from clones and their offspring; and on the import of semen and embryos of clones.

7. TRADE ISSUES

Breeding of the European bovine herd takes place mainly through artificial insemination. This has consequences on trade. Around 2.5% of the bovine semen used in artificial insemination in the EU is imported, of which approximately 99% from USA and Canada. According to the data available on TRACES (EU system to dispatch information set out in veterinary certificates accompanying animal and animal products traded within the EU and imported from third countries), the overall number of doses of bovine semen imported from USA and Canada into the EU in 2009 was above 1 200 000. These figures are supported by those for the first semester of 2010, with more than 600 000 doses of semen imported from these two countries.

Assuming that 50% of the doses of semen imported have been successfully used to inseminate cows in the EU in 2009, this means that around 600 000 calves born in the EU in 2010 are progeny of US or Canadian bulls. This amounts to approximately 2% of the calves born each year in the EU. There is no information about the number of doses of imported semen coming from cloned bulls.

Imports of embryos for embryo transfer and of breeding animals also take place. 747 consignments of bovine embryos were imported into the EU in 2009.

¹⁰ <http://www.copa-cogeca.be/Main.aspx?page=search&lang=en>

¹¹ <http://www.clitravi.eu/>

¹² Reference COM (2007) 872 of 7 January 2008

Imports of live bovines are much less common. In the first semester of 2010 only 24 breeding animals were imported into the EU (from Croatia and Canada)¹³.

For live animals, animal products (such as semen and embryos but also wool and leather) and food, the following multilateral agreements of the World Trade Organisation (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 (a) on the justification and (b) on the nature of the legislation to be drafted.

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), and the requirement to eliminate quantitative restrictions (Article XI GATT). Exemptions from these general rules can be justified under Article XX of GATT (*General Exemptions*) and/or the TBT or SPS agreement. The two latter would allow exemptions in line with international standards or based on scientific evidence. The potentially relevant international standard setting bodies for food safety (Codex Alimentarius) and animal health (World Organisation for Animal Health (OIE)) have not set relevant standards on cloning.

There is no scientific evidence which could justify restrictions on food from clones and food from offspring of clones based on human health concerns. EFSA has however expressed concerns which are related to the welfare of clones.

The most relevant exemptions from Article III and XI of GATT would thus be the exception on "public morals" which could include animal welfare (paragraph a GATT XX) or the protection of life and 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, non-trade restrictive manner.

8. LEGAL ASPECTS TO BE TAKEN INTO ACCOUNT IN THE RISK MANAGEMENT

Animal Health and Zootechnics

The applicable law, both veterinary and zootechnical, is based on Article 43 of the Treaty of the Functioning of the European Union. The rules do not distinguish between animals produced by different reproduction technologies (e.g. artificial insemination, embryo transfer, embryo splitting, in-vitro-fertilisation or cloning) as from a genetic perspective none of these practices affects the genome or susceptibility to infectious diseases.

¹³ Switzerland is not considered here, as in accordance with an agreement in place on veterinary issue, it is bound to apply EU legislation. Therefore trade in live animals with Switzerland takes place in accordance with the rules applying amongst Member States.

The basic aim of EU animal health legislation is to control infectious diseases. This legislation harmonises animal health conditions governing EU trade and imports from third countries. Animals and their products are traded with veterinary certificates. The certificates do not contain information about the reproduction technology by which the animal or (for semen, ova and embryos) the donor animal was produced.

The basic aim of EU zootechnical legislation is to improve livestock performance by rules to ensure free trade and harmonised conditions for imports of 'pure-bred' breeding animals and their genetic material. Pure bred breeding animals are traded with pedigree certificates containing the parentage of the animal. This legislation does not however affect the trade, imports or breeding of non pure-bred animals (representing some 95% of pigs, sheep and goats, 90% of beef cattle and 50% of dairy cattle).

EU zootechnical legislation establishes that pedigree certificates are issued by approved breeders' organisations or associations to ensure the ancestry, performance and genetic value of pure-bred breeding animals (bovine, swine, equine, sheep and goats) and their semen, ova and embryos that are traded within the EU or imported from third countries. These certificates do not foresee that information is given if the animals in question are clones/offspring of clones or if they are conventionally bred.

Animal welfare

Cloning could be examined in the light of the provisions of Council Directive 98/58/EC concerning the protection of animals kept for farming purposes. Paragraph 20 of the Annex to the Directive states that: "Natural or artificial breeding or breeding procedures which cause or are likely to cause suffering or injury to any of the animals concerned must not be practised." The same text is included in the European Convention for the protection of animals kept for farming purposes, which gives principles for the keeping, care and housing of animals, in particular in intensive breeding systems. Member States are responsible for the implementation of EU legislation on their territory. Furthermore, Article 13 of the Treaty of the Functioning of the EU clearly states that animals welfare needs must be fully taken into account when drafting and implementing EU policies on agriculture, fisheries, transport, internal market, research and development and space.

Traceability of animals

In the EU, food producing animals are subject to traceability requirements which also apply to clones. Individual traceability has been in place for bovine animals since 1997. For sheep and goats, individual traceability began in 2010. Pigs have been traceable on a batch basis since 1992. The current rules do not foresee a need to record on the documents any reference to reproduction technology.

Novel Foods issues

Food from clones is covered by Regulation (EC) 258/97 on Novel foods, since such food is derived from animals that are obtained by non-traditional breeding techniques. This means that these food products cannot be put on the market without a safety assessment and a specific authorising legal act. To date, no application has been made by any company seeking to put food from clones on the market.

Legislation on organic farming

Since 1991, the EU has in place a legislative framework relating to the practice of organic farming. At first the organic Regulation only regulated plant products. Additional provisions for the production of animal products were later introduced. These rules included animal feed, prevention of illness, veterinary treatment, animal protection, livestock breeding in general and the use of livestock manure¹⁴.

With regard to breeding, the Regulation states that reproduction shall take place using natural methods. However artificial insemination is allowed, but any other form of artificial reproduction, such as cloning and embryo transfer, shall not be used. The use of inducing treatments with hormones or similar substances is forbidden, unless in the form of therapeutic treatment for an individual animal.

The EU framework on organic farming provides for the guarantee that food is obtained from animals bred without the use of any "non-traditional breeding method" such as cloning or embryo transfer.

9. OPTIONS

The assessment of the situation shows that it is scientifically accepted that there are no food safety concerns about food produced from clones or their offspring. The risks for animal welfare are however a solid basis for the Commission to initiate a legislative process. To address the concern that people perceive the cloning of animals as morally wrong could be seen as another factor to be taken into account under EU law.

The options are therefore:

(1) *Legal status quo*

Cloning would continue not to be specifically regulated at EU level. Clones and their reproductive materials (semen, ova and embryos) would continue to be marketed in the EU under the general rules. Food from clones would still be subject to a pre-market authorisation under the Novel foods Regulation. Food from the offspring of clones would continue to be covered by generic rules, which ensure the safety of those products and the functioning of the single market¹⁵.

¹⁴ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.

¹⁵ Treaty of the Functioning of the EU, Art. 34 – 36, General food law Regulation (EC) No 178/2002 on the general principles and requirements of food law, Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Regulation (EC) No 853/2004 on the specific hygiene rules for food of animal origin.

(2) *Total prohibition*

- **Prohibition of the cloning of farm animals for food production:** This would address the key issue pertaining to cloning, namely the welfare concerns. Cloning would not be allowed on EU territory for food production purposes.
- **A ban in the EU on the use of clones and of the placing on the market of food from clones:** This measure, which would also apply to imports would ensure coherence with the ban of the cloning technique in the EU.
- **A ban of the placing on the market of offspring of clones and food from the offspring of clones:** This measure would not be justified on grounds of protecting animal welfare, animal health or public health in so far as there are no welfare concerns for the offspring of clones as they are produced by normal reproduction techniques, nor safety concerns for food derived from offspring of clones, as indicated by EFSA. As food from the offspring of clones cannot be distinguished from food from other animals, a complete traceability system would be needed. This would be extremely burdensome to put in place as it would imply detailed tracing of all generations of offspring, for the species used for food production. Furthermore, such prohibition would lead to a ban of imports of any food of animal origin (meat, milk and processed products), from third countries which may have imported reproductive material from clones. A total ban on the import of food from the offspring of clones would have a considerable and disproportionate economic impact on EU agriculture production and trade. In addition, there are no welfare or health or food safety concerns to justify such action.
- **A ban on the use of reproductive material from clones:** There are no health or food safety concerns linked to the use of conventional breeding techniques, therefore a ban on imports of reproductive material from clones is difficult to justify.

(3) *Mix of measures*

The Commission considers that a mix of measures would meet the concerns raised on the issue of cloning. These measures could include:

- **A temporary suspension of the cloning technique of farm animals for food purposes:** This option addresses the welfare issues linked to the use of the cloning technique for food production in the EU. As the technique may mature and alleviate partially or fully these concerns, the prohibition should be revisited after a certain period.
- **A temporary suspension of the use of cloned farm animals:** This is a limited measure since imports of live clones are rare and no commercial cloning occurs in the EU. This would ensure coherence with the suspension of the cloning technique.

- **A temporary suspension of placing on the market of food from clones:** This suspension which would apply also to imports would ensure coherence with the ban of the technique in the EU.
- **Traceability of reproductive material:** This would allow farmers and the food industry to develop information schemes. In order to distinguish between (i) semen and embryos from clones and (ii) semen and embryos originating from conventionally bred-animals it would be necessary to amend certain certification requirements laid down in the zootechnical and animal health legislation. As operators would be required to mention in existing certificates whether or not the reproductive material derives from a clone, the administrative burden is limited. Such information is not difficult to retrieve as the genetic value is usually requested by the purchaser. Further, some trading partners using the cloning technique for food production purposes have already established - or envisage to do so - a specific system of compulsory registration of clones, which facilitates further the traceability of reproductive material.

10. CONCLUSIONS

In view of the issues outlined above, and in particular the need to address the welfare concerns linked to the use of the cloning technique and the appropriateness to allow market information, the Commission will propose to:

- (i) Suspend temporarily the use of the technique in the EU for the reproduction of all food producing animals; the use of clones of these animals; and the marketing of food from clones.
- (ii) Establish the traceability of imports of semen and embryos to allow farmers and industry to set up data bank(s) of offspring in the EU.

With a review clause after 5 years, the proposed legislative measure will be based on the appropriate legal basis taking into account its content and objective. Cloning would however remain possible for all other purposes than food production such as research¹⁶, production of pharmaceuticals or the conservation of endangered species or breeds. During the five year period, the Commission will monitor the scientific and technological development of cloning in order to assess whether, when and under which conditions these provisional measures could be removed. No legal measures are proposed in relation to food from the offspring of clones. However, the establishment of the traceability system under (ii) above makes information schemes possible.

¹⁶ The use of clones in research must be in compliance with the Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

The future scenarios can be summarised as follows:

	Clones			Offspring		
	Clone itself	Embryo/semen	Food products	Offspring itself	Embryo/semen	Food products
Produced in the EU	Temporary suspension of the technique for food production	No measure As long as the technique is suspended there will be no products (embryos, semen, food) of clones produced in the EU and of their offspring				
Imported in the EU	Temporary suspension of imports of clones	Traceability requirements on exporters to EU	Temporary suspension of placing on the market.	No measure		

The Commission invites the Parliament and the Council to consider the contents and conclusions of this report and to express their positions in due course.