

ROADMAP

Title of the initiative: **Report on cloning to the European Parliament and the Council**
Type of initiative (CWP/Catalogue/Comitology): report (listed under the CWP)
Lead DG: SANCO
Expected date of adoption of the initiative (month/year): December 2010
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Initial IA screening & planning of further work

A. Context and problem definition

(i) What is the political context of the initiative? (ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?

Cloning of animals is a new reproduction technique which allows making copies of valuable animals.¹ This could be animals that already have shown good productivity, a low incidence of disease and ability to cope with the production environment. However, as with any breeding strategy it is important to carry out longer term risk assessments on critical aspects and to address any kind of potential risks in relation to the potential benefits taking into account legitimate socio-economic factors, the welfare of the animals and factors related to this. Furthermore the correlation between cloning and food security has to be addressed.

In relation to food safety, cloning currently is covered by the existing regulation on Novel foods, which request a pre-market authorisation before the food products derived from cloned animals can be put on the European market.

The Commission already took important steps to address all aspects of the use of cloning for food production: EFSA was asked to assess the animal health and animal welfare issues, as well as environmental and food safety aspects. The European Group of Ethics was asked to present an opinion on the ethical problems raised by the use of animal cloning and a Eurobarometer was made by the Commission in order to know consumer's attitudes and views on such new technology.

The Council Common Position extends the scope to include the offspring of cloned animals and provides for the Commission to submit a report to the Council and the Parliament on all aspects of food produced from animals obtained by using a cloning technique and from their offspring, followed, where appropriate, by any legislative proposals. The report is to be presented one year after the entry into force of the Regulation.

The situation is evolving at international level. Several trade partners as the US and Japan have finished their safety assessment and are ready to take market management measures. The trade of cloned live animals, and their semen and embryos is taking place on the world market.

In view of the highly politically sensitive issue, both the Council and the EP have asked for a thorough review of the cloning of animals for food production. **The Commissioner promised to the Parliament, during his hearing, to submit this report by the end of 2010.**

The report will consider all aspects of cloning for food production in the context of existing legislation and will point out possible options after an in depth consultation of stakeholders. The issue is to address the need, the feasibility and the proportionality of measures proposed to regulate the use of the technique and products obtained thereof. It will also review all the science based issues concerning the health and welfare of the animals.

¹ Cloning in this context is understood as somatic cell nuclear transfer (SCNT).

What are the main problems identified?

Even if the public debate is primarily focused on food safety, health and welfare of the animals, the main resentments are of ethical nature.

On the other hand animal cloning is about to become a commercial reproductive technology, like in-vitro-fertilization and embryo transfer. It may further develop and be practiced in many parts of the world.

This politically sensitive issue has raised several questions as regards the health and the welfare of the animals, consumer's right to know and the interest of the sectors involved in cloning.

Issues as the ethical dimension and the "consumer's right to know" about the production process must be taken into account. If the report identifies future challenges that need further action, the Commission will have to consider the impacts of such actions.

The report should also consider future challenges as regards the trade (inside the EU and with third countries) of semen, embryos and food from clones and their offspring.

In relation to the revision of the Novel Foods regulation, another issue to be noted is that the Commission opposes to the text of the Council Common Position as regards the inclusion of the first generation of offspring from cloned animals in the scope of Regulation.

Who is affected?

The following will have an interest in the subject: breeders, farmers, food industry, biotech industry, research community as well as consumers, animal welfare and animal health organisations and trade partners.

In the Commission AGRI, TRADE, RTD, BEPA are the most concerned services as well as SG and LS

(i) Is EU action justified on grounds of subsidiarity? (ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)? (iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?

Commissioner Dalli has promised to the EP to present the report on cloning before the end of this year. In addition this is foreseen by the Council as it stands in the Common position. Because of the potential internal market and trade dimensions of the cloning issue, EU action may be warranted.

On the other hand, possible future initiatives concerning the technique itself, if they are based on ethical grounds alone, may justify leaving the issue to the actions of Member States.

Action at EU level regarding the use of the technique would need to be assessed in the light of related issues; the health and the welfare of the animals, ethical concerns and the consumer's right to know. Should any legislative proposals be warranted, Impact Assessment will be carried out in accordance with Commission guidelines.

B. Objectives of EU initiative

What are the main policy objectives?

The objective of the report is to provide the basis for a broader political debate on the need and advisability to develop new policies so as to address issues raised by the use of cloning in food production.

Do the objectives imply developing EU policy in new areas or in areas of strategic importance?

Possibly yes depending on the conclusions of the report and the outcome of the political debate.

C. Options

(i) What are the policy options? (ii) What legislative or 'soft law' instruments could be considered?
(iii) Would any legislative initiatives go beyond routine up-date of existing legislation?

The report will endeavour to describe, to the extent possible, the current situation and the future applications of the cloning technique for food production. We highly depend on a sound analysis of the state of play in science and practical application and the input and information given by stakeholders and relevant parties. We will analyse different scenarios and look at possible future initiatives. Stakeholders will be consulted

Will the current regulatory situation be sufficient to cover the challenges of the use of the cloning technique for food production?

The cost and benefits of enforced traceability schemes and labelling of products from clones and offspring of clones must be considered.

Based on the analysis and the input received in the consultation of stakeholders, the most relevant options will have to be identified for further assessment. It is not clear at this stage whether legislative measures are appropriate.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

There are links between cloning (as a new breeding technique) with DG AGRI and RTD.

Explain how the options respect the proportionality principle

The report, promised by Commissioner Dalli, as such respects the proportionality principle. It is also foreseen by the Council Common position and is related to provisions foreseen at EU level. Depending on the stakeholder's consultation and the possible definition of options, it will be necessary to ensure at that stage, that these respect the proportionality principle.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?

After the consultation of stakeholders on the issue, we might have to look at the possible options and their respective impacts.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Probably not.

Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries?

The possible options will need to be assessed, in particular as regards relations with third countries, as the USA is the leading country which has introduced the cloning technique.

E. Planning of further impact assessment work

When will the impact assessment work start?

IA should be started for follow-up proposals if the political debate initiated by the report leads the Commission to the conclusion that a legislative proposal or other EU action should be prepared.

(i) What information and data are already available? (ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out? (iii) What further information needs to be gathered? (iv) How will this be done (e.g. internally or by an external contractor) and by when?
(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

At present we have official information that there are no products from cloned animals on the EU food market.

We have opinions and assessments from the European Food Safety Authority and other food safety agencies. In addition we have the opinion from the European Group of Ethics and the citizen's attitude from the Eurobarometer.

Which stakeholders & experts have been/will be consulted, how and at what stage?

For the purpose of gathering information on the present situation on the use of cloning for food production, the Commission will consult different stakeholders with an interest in this technique. Members of the Advisory Group on the food chain and animal and plant health will be consulted as well as other relevant stakeholders, ethicists, consumer organisations, trade partners and companies using the technology. Stakeholders will also be consulted after the publication of the report.