European Food Safety Authority

The cloning of animals: animal health, welfare and food safety

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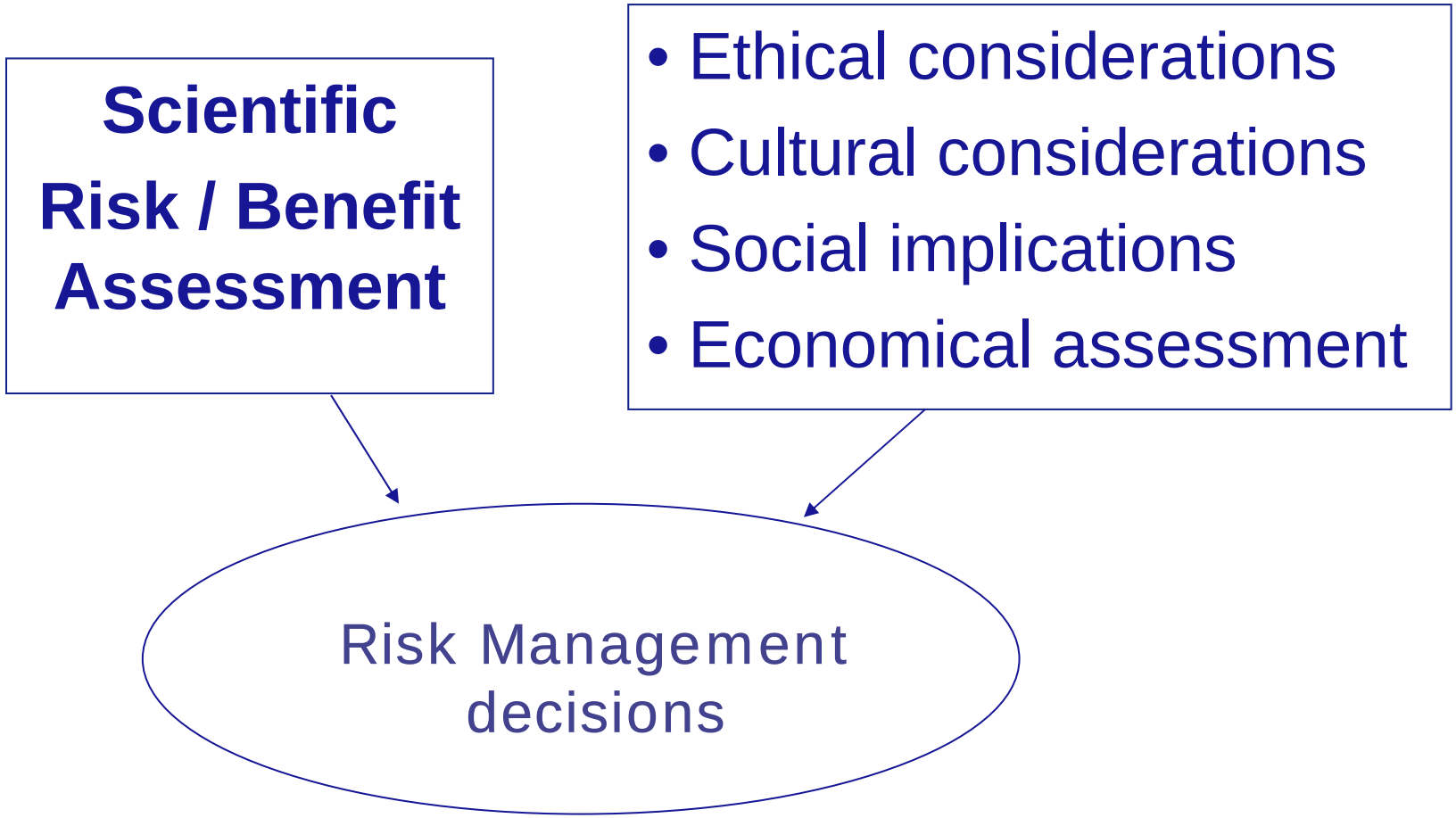
Risk assessment and risk Management



Ethical assessment

EFSA was not established to address ethical questions and does not have the competence to assess ethical issues.

Therefore, EFSA does not consider ethical aspects in any of its assessments and subsequent opinions or advice.

Ethical issues: assumptions

For instance, in EFSA's scientific assessments it is assumed that:

- The use of experimental animals as surrogates for humans in hazard characterisation is, in principle, accepted.
- The breeding and use of animals for animal and human consumption is, in principle, accepted.
- The fundamental concept of modification of the genetic make-up of an organism resulting in essential genotypical and consequent fenotypical differences in the organism as compared to its natural fenotype is, in principle, accepted

Ethical issues: misconceptions

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Animal Health and Welfare Panel:

- Assessment of animal welfare risks is very easily confused with ethical evaluations;
- However, welfare of animals is assessed (ideally quantitatively) against an assumed ethically acceptable reference standard;
- To a large extent ethically acceptable reference standards are culturally defined.

Commission request for an opinion on cloning

Terms of reference:

…to advise on food safety, animal health, animal welfare and environmental implications of live cloned animals, obtained through somatic cell nuclear transfer technique (SCNT), their offspring and the products obtained from those animals.

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Main issues:

- Technology of transferring the intact nucleus of a somatic cell into an enucleated oocyte;
- Health and welfare of the foster mother and the cloned animal;
- Characterization of the genetic make-up of the cloned animal, considering both intranuclear and extranuclear (mitochondrial) genetic material;
- Comparative physiology of cloned and conventional animals, including reproductive capacity;
- Safety of consumption of cloned animals and their products (meat, milk products, eggs);

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Main issues (2):

- Characterization of the genetic make-up of the offspring of the cloned animal;
- Comparative physiology of the offspring of cloned and conventional animals;
- Health and welfare of the offspring of cloned animals;
- Safety of consumption of offspring of cloned animals and their products (meat, milk products, eggs);
- Environmental implications.

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Animal species covered:

- Captive large ruminants (cattle);
- Captive small ruminants (goats, sheep);
- Captive swine;
- Oviparous animals (birds, among which primarily chicken).

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Core expertise required:

- Genetics (including genetic characterisation, population genetics);
- Animal biotechnology (including transgenic processes);
- Toxicology (including food and reproductive toxicology);
- Developmental biology (including embryology, endocrinology);

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Core expertise required:

- Assisted animal reproduction technology (including breeding genetics);
- Animal health;
- Animal welfare.

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Additional expertise most likely required:

- Nutrition (to assess i.a. deficiencies, comparative nutritional values);
- Biological hazards (to address i.a. food borne diseases, antibiotic needs, resistance);
- Immunology (to address i.a. immune suppression);
- Environmental assessment (to address i.a. environmental fate, toxicology).

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Selection of appropriate experts to be involved in the work:

- From the Scientific Committee and respective Expert Panels;
- External experts from US.FDA and the French AFSSA;
- Other well-recognised scientific institutions.

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Scientific input required from:

- Academia (agricultural, veterinary, biological sciences);
- Well-recognized public animal breeding institutes in the EU, USA and elsewhere;
- Experts affiliated with commercial (industrial) animal breeders;
- Experts from NGOs (consumer, environmental protection, animal welfare).

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Work approach:

- Project will be managed by the Scientific Committee;
- Preparatory work (draft opinion) will be carried out by a Working Group of the Scientific Committee;
- Working Group composition will be the responsibility of the Scientific Committee;
- Working Group will be chaired by the Chair of the Scientific Committee.

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Work approach (2):

- Work will start with a public request for input of relevant data/information through a web consultation;
- Working Group may wish to meet parties which provided particularly relevant input through the consultation;
- Draft opinion will address the cloning, the food safety and animal health and welfare aspects of cloned animals and their offspring;

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Work approach (3):

- The draft will be open for comment and public review, likely to be followed by a public consultation meeting;
- Depending on the outcome of the draft opinion and the subsequent public consultation(s) the draft will:
  - (i) be finalised, taking into account all comments and suggestions; or
  - (ii) need further work based on the initial safety assessment, possibly including nutritional, biological hazards, immunological and environmental assessments.

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Working together:

- EFSA will work closely with the French AFSSA and the USA FDA;
- Animal welfare and environmental implications were not considered in FDA report;
- Aspects of the FDA Report that need to be scrutinized include:
  - how are 'normal' and 'healthy' defined in the context of cloned animals and their progeny ;
  - details of data used (source, date, level of detail, statistics);
  - details of exposure assessment and hazard criteria.

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Furthermore:

- EFSA would appreciate to stay in close contact with the European Group on Ethics in Science (EGE);
- The request for the opinion was received on 1st March 2007 with a deadline of 1st August 2007;
- It is very unlikely that EFSA can finish the work in 5 months: the Commission will be informed of a more realistic time frame after 17th April.