



Embryo and embryonic stem cell research in France

A new legal framework since 2004

- **In 1994 the first bioethics law was voted by the French national Assembly** (organ transplant, assisted reproduction technologies (ART), prenatal and genetic diagnosis):

Embryo research is strictly prohibited

- **Review of the bioethics law in August 2004**
 - ✓ Principle: embryo and embryonic stem cell research remains prohibited but the Agence de la biomédecine has been empowered to give dispensations since the decree of 2006.
 - ✓ Political compromise
- Experiment for 5 years: at the end of this period the law will have to be reexamined by the French Parliament

Conditions for getting license

Two crucial conditions:

- Researches must result in significant therapeutic progresses,
- Alternative method with similar efficiency must not be able to replace these researches.

Conditions for the couple's consent

- Supernumerary embryos with no more parental project
- Given to research by the parents:
 - Informed and reiterated consent
- Healthy, pathological or non transferable (into the uterus) embryos (morphological problems)

The missions of the Agence de la biomédecine

Authorisations granted by the Agence de la biomédecine according to the decision of the committee on ethics (« conseil d'orientation »)

The committee on ethics is made up of 25 members:

- 1/4 of people representing institutions (National Assembly, Senate, supreme administrative jurisdictions...)
- 1/4 of scientists and medical doctors specialised in organ transplant and ART
- 1/4 of people representing human sciences (jurists, psychiatrists, philosophers...)
- 1/4 of people representing associations of patients

Three types of accreditation

- *Research*: the quality of the scientific protocol and the conditions of consent of the parents are closely examined
- *Conservation*: data on premises with a capacity of embryo storage for several teams (bank?)
- *Import* of derived hESc lines from abroad

The General Director's Powers

- General obligation to follow-up the ongoing works: research teams must send a yearly report to the Agence which in turn may ask for additional information.
- The Agence may send inspectors to the premises
- The General Director of the Agence may suspend or withdraw the authorisation in case of violation of the legal or regulatory clauses or of the instructions determined by the authorisation

CONCLUSION

- **Number of authorised teams: 29**
- **Number of decisions delivered since 2005 :**
 - 25 import licenses
 - 34 research licenses
 - 15 conservation licenses
 - 6 refusals