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Press release
Saint-Denis, February 7th 2006

Publication of the decree relating to research on human embryos and embryonic stem cells

The decree published today in the French *Journal Officiel*, defines the authorisation procedure for research on human embryos and embryonic stem cells in line with the bioethics law of August 2004. From now on, the *Agence de la biomédecine* (the French Biomedicine Agency) will be responsible for authorising such research in France. The first dossiers may be sent to the appropriate department in March 2006. Two other periods when dossiers may be sent will be proposed during 2006.

The end of temporary arrangements

Since September 2004, the French Ministries of Research and Health have delivered 40 authorisations for such research, thanks to temporary arrangements specified in the bioethics law. These arrangements exclusively concern research carried out on embryonic stem cell lines created abroad. Authorisations are delivered following approval by an *ad hoc* committee and have enabled about 10 teams to begin research on stem cell lines of foreign origin[1]. Several tens of stem cell lines have been produced in other countries, from fresh or frozen embryos, with and without genetic diseases. The French Biomedicine Agency will now take over the role of the *ad hoc* committee and will be responsible for monitoring the protocols authorised by this committee.

Tightly controlled research

The bioethics law of August 2004[2] prohibited research on human embryos[3]. However, the new decree makes provision for special dispensation to be given, for a five-year period: "*Research on embryos and embryonic stem cells may be authorised if such research is likely to facilitate major progress in treatment and could not be carried out by an alternative approach of comparable efficacy, in the current state of scientific knowledge".*[4]

The task of authorising and controlling research on human embryos and embryonic stem cells has been assigned to the French Biomedicine Agency.

[1] In total, 40 authorisations have been delivered by the *ad hoc* committee: 14 authorisations to import human embryonic stem cells, 17 authorisations for study or research protocols and 9 authorisations for the storage of these cells.
[2] 2nd part of book I Title V "Research on the embryo and embryonic cells".
[3] By research on the human embryo, we mean all scientific manipulations going beyond simple observation. The manipulated embryo — like all embryos used for studies — cannot be reimplanted in a woman for the purposes of pregnancy.
[4] Article L. 2151-5 of the French public health code

The decree published today opens up many new possibilities for researchers, within the framework of French law. In particular, it allows researchers to create and to work on lines of human embryonic stem cells from spare embryos of French origin no longer needed for fertility treatment purposes and on cell lines imported from other countries and created in the same conditions.

Only embryos conceived *in vitro*, in medically assisted procreation programmes can be used to this end. Three situations should be distinguished:

- Spare embryos no longer required for fertility treatment purposes. The "parents" must give written consent for the donation of the embryo for research purposes, without remuneration. This consent, once given, must be reaffirmed after a three-month reflection period.
- Embryos in a condition unsuitable for reimplantation or for storage for a future pregnancy, provided the "parents" give their authorisation.
- Embryos carrying an abnormality screened for in preimplantation diagnosis (PID), provided the "parents" give their authorisation.

At the end of the five-year trial period, the French Biomedicine Agency and the parliamentary office for the evaluation of scientific and technological choices will each produce an evaluation of the research carried out, enabling the French Parliament to re-examine the provisions of the bioethics law.

Embryo and embryonic stem cells: the fields in which the French Biomedicine Agency will intervene
The mission of the French Biomedicine Agency is to assure the authorities and citizens of France that research on the human embryo, and the cells derived from it, are carried out ethically, safely, and with the required high level of quality and transparency, strictly respecting the bioethics law.

In practice, the French Biomedicine Agency will be responsible for authorising, controlling and monitoring research and for ensuring traceability.

- *Authorisation*: The French Biomedicine Agency will study and authorise research protocols proposed by French scientific teams. It will also authorise the importation, exportation and storage of human embryonic stem cells.
- *Traceability*. The French Biomedicine Agency will guarantee the identification and traceability of human embryos used for research, and of embryonic stem cell lines created from these embryos or imported from abroad.
- *Control*. The French Biomedicine Agency will control the authorised activities, with the possibility of carrying out inspections, or of suspending or definitively halting the work.
- *Monitoring*. Each team authorised to carry out research in this area must send the French Biomedicine Agency an annual report of its work. These reports will be examined by the Agency.

Consideration of the scientific and ethical stakes of research work on human embryos and embryonic stem cells is at the heart of the missions of the French Biomedicine Agency.

For the completion of this mission, the French Biomedicine Agency will make use of its orientation council (*le conseil d'orientation*), a unique structure among French health authorities.

The orientation council brings together scientific and medical experts, experts in social sciences, representatives of associations, politicians and representatives from diverse institutions[5]. It ensures the coherence of the medical and scientific policies of the Agency and respect for the regulatory and ethical principles relating to its activities. It will examine every research project or study on the embryo or embryonic stem cells and will give an expert opinion before the decision concerning authorisation is taken.

Research on the embryo and embryonic stem cells: the stakes

Embryonic stem cells are obtained from the human embryo at the very earliest stages of its development (several days old, at the blastocyst stage). They are cultured *in vitro*, in an appropriate environment.

Biologically and medically[6], these cells are a source of hope for progress in:

- Understanding of the very early stages of human development;
- Understanding the biological mechanisms controlling the self-renewal characteristic of these cells and the differentiation of these cells into different types of cells;
- The development of new means of treatment in the longer term.

Press contacts:

Bénédicte Vincent: 00 33 (0)1 55 93 69 34; Fabienne Tong: 00 33 (0)1 55 93 64 96

[5] Including the National Ethics Consultative Committee and the Consultative Committee on Human Rights

[6] Research work is also carried out on stem cells obtained from differentiated tissues ("adult" stem cells).

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Research on human embryos and embryonic stem cells

The procedure supervised by the French Biomedicine Agency

The authorisation and control of research

All dossiers requesting authorisation for research protocols should be sent to the Director General of the French Biomedicine Agency, during the periods .set by the Agency. Each dossier will be examined by scientific experts. The report of those scientific experts will be sent to the orientation council of the Agency, which will deliver its verdict. The Director General will take the final decision. This decision, accompanied by the verdict of the orientation council, is sent to the health and research ministers. If the request for authorisation is rejected, the health and research ministers may ask the French Biomedicine Agency to reconsider the dossier. If the request for the authorisation is accepted, the ministers may cancel or suspend the proceeding of the dossier if its scientific pertinence is not established and if ethical principles are not respected.

Once a protocol has been authorised, the person responsible for the research must send to the Agency an annual report concerning the progress of the work and a final report at the end of the authorisation period. If the protocol is modified during the research, the proposed modifications must be submitted to the French Biomedicine Agency, for examination, according to the same procedure as the initial request for authorisation.

The French Biomedicine Agency is also responsible for controlling the research and may carry out inspections. If the conditions of the authorisation are not respected or if legal or regulatory principles are violated, the research may be suspended at any time, for a period of up to three months, by the Director General of the Agency. The Director General will notify the orientation council of any such decision. Authorisation may also be definitively withdrawn, on the advice of the orientation council. Before any decision to suspend or withdraw authorisation is taken, the holder of the authorisation will be told to .correct the problem or to explain the reasons for not doing so within a period of time determined by the Director General.

Exchange and storage of cell lines

Research activities require access to appropriate human stem cell lines and the ability to store these lines *in situ* or in a partner organisation, with an established storage convention.

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These activities now also come under the control of the French Biomedicine Agency, which will thus be responsible for overseeing both research on human embryos and embryonic cells and the activities underlying this research.

Importation and exportation. All organisations wishing to import embryonic or foetal tissues or cells must hold an authorisation for research on or the storage of this material. They must also ensure that the ethical principles enshrined in law are respected (consent of the "parents", absence of remuneration etc.). The Agency will also deliver authorisations for the exportation of these tissues and cells.

All importations or exportations authorised by the French Biomedicine Agency, on the advice of the orientation council, must take place during the 12 months immediately following authorisation.

The decree published today also concerns the importation of tissues and cells of embryonic or foetal origin obtained following abortion[7].

Storage. Authorisations to store embryonic stem cells are valid for a limited, defined time period, not exceeding five years. Throughout the period of authorisation, the French Biomedicine Agency has the right to carry out checks of the storage conditions, as a means of guaranteeing quality and safety.

Traceability and identification of cell lines. The French Biomedecine Agency is committed to the establishment of a national register of human embryos and embryonic cells. The necessary information will be supplied by the organisations authorised to import or to create such lines. These organisations must also keep a register of the biological material held.

Identification systems ensure the traceability of the embryos and cells delivered, whilst guaranteeing the anonymity of the individuals from whom the embryo was obtained.

[7] The bioethics law provides for the possibility of research on these tissues and cells. The corresponding protocols must be transmitted to the French Biomedecine Agency before their implementation. No authorisation for this type of research, as such, can be delivered by the French Biomedecine Agency. Instead, the French Biomedecine Agency will communicate a list of these protocols, or its opinion concerning these protocols, to the Minister for Research. This minister may suspend or prohibit research projects if their scientific pertinence is not considered demonstrated or if ethical principles are not respected.

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Human embryo and human embryonic stem cells (hES cells) research
Regulations in EU Member States regarding hES cell research

	Allowing procurement of hES cells from supernumary embryos by law	Specific legislation for human embryo research including supernumerary embryos but without specific reference to hES cells	Prohibiting procurement of hES cells from human embryos but allowing importation of hES cell lines	Prohibiting procurement of hES cells from human embryo	No specific legislation regarding human embryo research	Allowing creation of human embryos for procurement of hES cells by law	Prohibiting creation of human embryo for research purpose and for procurement of hES cells*
Austria				X			X
Belgium	X					X	
Cyprus					X		X
Czech Republic					X		X
Germany			X				X
Denmark	X						X
Estonia		X					X
Greece	X						X
Spain	X						X
Finland	X						X
France	X						X
Hungary		X					X
Irland					X		X
Italy			X				X
Lithuania				X			X
Luxembourg					X		
Latvia		X					
Malta					X		
Netherlands	X						X
Poland				X			
Portugal					X		X
Sweden	X					X	
Slovenia		X					X
Slovenia					X		X
United Kingdom	X					X	

Source : European Commission – General Directorate for Research (updated august 2005) * Convention of the Council of Europe on Human rights and Biomedecine signed in Oviedo on 4 april 1997

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Research on human embryos and embryonic stem cells

State of legislation worldwide

Research on human stem cell lines created from spare embryos originating from *in vitro* fertilisation programmes		
Research authorised *Cloning authorised*	*Research authorised* *Cloning prohibited**	*Research limited*
United States (non-Federal funding) China India Israel Singapore South Korea United Kingdom	Australia Brazil Canada France (under special dispensation) Japan Switzerland Taiwan	United States (with Federal funding)** Germany (imported embryonic stem cells only, under special dispensation)

* The degree of legal restriction depends on the country concerned.

** Research is nonetheless possible, using stem cell lines established before August 2001.

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The missions and organisation of the French Biomedicine Agency

The French Biomedicine Agency is a public administrative organisation under State control, overseen by the Minister for Solidarity, Health and Family. This organisation is competent in the domains of organ, tissue and human cell transplantation, procreation, embryology and genetics, and fulfils the following roles:

- Monitoring, evaluating and controlling therapeutic and biological activities relating to its areas of competence and ensuring their transparency;
- Participation in the development of regulations for activities relating to its areas of competence;
- Delivering authorisation for research *in vitro* on embryos and embryonic cells and for the storage of embryonic stem cells for research purposes;
- Authorising the exchange with other countries of reproductive cells or embryonic stem cells for research purposes;
- Delivering authorisations to pluridisciplinary antenatal diagnosis centres and preimplantation diagnosis centres;
- Accrediting practitioners in the fields of medically assisted procreation, antenatal and preimplantation diagnosis and examinations of genetic characteristics;
- Taking over all the activities of the *Etablissement français des Greffes* (the French Transplantation Agency) concerning graft harvesting and transplantation;
- Managing, with all the required guarantees, the information required for the management and monitoring of treatment activities related to its areas of competence;
- Promoting human organ, tissue and cell donation and the donation of gametes (sperm and ovules).

An organisation providing expert advice and proposals, and the capacity to take decisions
The French Biomedicine Agency is headed by a Director General nominated by decree. It has a management board comprising representatives from various ministries and public health administrations and individuals qualified in the domains of competence of the French Biomedecine Agency.

The French Biomedicine Agency also has an orientation council, a body responsible for providing advice and taking decisions, which ensures the coherence of the medical and scientific policy of the agency and guarantees that the ethical and legal principles applying to its activities are respected. The French Biomedecine Agency obtains medical and scientific expert advise from a medical and scientific committee and . expert groups.