Examples of bioethics legislation (France case).

It has been noted that French legislation has taken a number of different positions, the last of which were the result of lengthy and hard doctrinal, ethical and legal reflection, and the Estates General on Bioethics, together with certain previously existing legislation, such as the Veil law on abortion in 1975, the Cavaillet law of 1976 on organ and tissue transplantation, and the Huriet-Sérusclat law, which did not contain many innovations compared with the previously known international legal framework .

The first unifying legal instrument linking bioethical issues was the 1994 bioethics laws, followed by the law of 6 August 2004, and finally the 2011 legislation, which will be amended with new points.

1. Medically assisted procreation :

Medically assisted procreation refers to clinical and biological practices enabling in vitro conception, the preservation of gametes, germ tissue and embryos, embryo transfer and artificial insemination.

Article L. 2141-2 states that the purpose of medically assisted procreation is to remedy a couple's infertility, or to prevent the transmission to the child or to a member of the couple of a particularly serious disease. The pathological nature of the infertility must be medically diagnosed" and again: "The man and woman forming the couple must be alive, of childbearing age, and consent to the embryo transfer or insemination beforehand. The death of one of the members of the couple, the filing of a petition for divorce or legal separation, or the cessation of cohabitation, as well as the written revocation of consent by the man or woman to the doctor responsible for implementing medically assisted procreation, are obstacles to the insemination or transfer of embryos".

In France, surrogate motherhood is not authorised because it is contrary to the principle of the indisponibility of the status of persons, an essential principle of French law. Article 16-5 of the French Civil Code states that contracts that have the effect of conferring a pecuniary value on the human body, or on the status of a person, are prohibited.

the human body, its elements or its products are null and void. Article 16-7 of the Civil Code states that agreements relating to procreation or surrogate motherhood are null and void. This means that they cannot produce any legal effect.

In vitro conception must be carried out using gametes from at least one of the two members of the couple (double donation by third parties is prohibited). However, to avoid unlimited storage of embryos, each year both members of the couple will be consulted in writing to find out whether or not they are maintaining their parental project. If they do not, there are three possible solutions: destruction, consent to donate the embryo to research, under certain conditions, or donation to another couple.

2. Prenatal diagnosis :

The article L. 2131-1 of the CSP in force until 2011 is the one passed in 1994, unchanged by the legislative revision ten years later. This is simply a general definition of PND, which "refers to medical practices aimed at detecting a particularly serious condition in the embryo or foetus in utero". There is no question of an obligation to provide information or prescribe, and no foetal pathology is directly or indirectly designated. The same law contains article 16-4 of the Civil Code, which unambiguously condemns eugenics: "Any eugenic practice aimed at organising the selection of persons is prohibited".

It is moving in the direction of generalising this screening, since from now on, "All pregnant women shall receive, during a medical consultation, fair, clear information tailored to their situation about the possibility of having recourse, at their request, to medical biology and imaging tests to assess the risk that the embryo or foetus has a condition likely to affect the course or monitoring of their pregnancy".

3. Pre-implantation diagnosis :

PGD has been authorised in France since 1999 and is aimed at couples whose offspring present a significant risk of a serious and incurable genetic disease (myopathy, cystic fibrosis, thalassaemia, sickle cell anaemia, etc.). The aim is to differentiate affected embryos from healthy or unaffected carriers, before re-implanting them in the uterus.

The genetic study is carried out on embryos obtained by in vitro fertilisation. PGD was conceived and developed as an alternative to medical termination of pregnancy (IMG) whenever possible.

The Article L2131-4 states that it cannot take place without a doctor working in a prenatal diagnosis centre certifying that the couple, due to their family situation, has a high probability of giving birth to a child suffering from a particularly serious genetic disease recognised as incurable at the time of diagnosis. The diagnosis can only be made when the anomaly or anomalies responsible for such a disease have been previously and accurately identified in one of the parents, or in one of their immediate ascendants in the case of a severely debilitating, late-onset and prematurely life-threatening disease. This diagnosis is made only in the context of treatment and prevention, and in an authorised establishment.

4. Anonymity of gamete donation :

Surveys carried out in 2006 and 2008 among 1,524 recipients and 226 donors confirmed their support for the principle of anonymous donation. The CECOS therefore did not consider it urgent to change the law, just like the members of parliament who, in July 2011, maintained the anonymity of gamete donations in France. The French legislator wanted to make the situation of gamete donors more secure. The absolute rule of anonymity was thus

reaffirmed following the major parliamentary debates in the first half of 2011, with a view to revising the Bioethics Act.

No filiation link can exist between the donor and the child born from the donation; similarly, the obligation for recipient couples to give their consent before a judge or notary before resorting to third-party donor MPA prevents them from contesting filiation at a later date.

In November 2014, the ABM launched a national campaign to encourage gamete donation and encourage everyone to consider becoming a potential donor. Gamete donation is possible for women aged between 18 and 37, and men aged between 18 and 45, who are in good health and have already had a child. It is carried out in health establishments, on the advice of the ABM, for this activity. It is subject to the three ethical principles common to all donations from the human body: free consent to donation, anonymity and no charge.

5. Genetic examinations for medical purposes :

The law authorises a person's relatives (close family) to be informed of the serious genetic disease affecting their family member. In particular, it states that the person may express their wish in writing to be kept in ignorance of the diagnosis. However, it also imposes an obligation on the person to inform, either directly or through the prescribing doctor, any family members who may be affected, as soon as preventive measures or care may be offered to them.

Genetic tests may only be carried out by authorised and accredited laboratories. Any person requesting an examination of his or her genetic characteristics or those of a third party or the identification of a person by genetic fingerprinting outside the conditions laid down by law is liable to a fine of €3,750.

6. Termination of pregnancy:

French law distinguishes between voluntary termination of pregnancy and termination of pregnancy for medical reasons (in particular in the event of an abnormality in the embryo). It is worth highlighting the apparent paradox that the same premises (the embryo is a potential person) lead :

- in the case of a "normal" pregnancy, to consider that it must be carried to term, unless there is a strong reason (in French law: the mother's "distress"), hence a relatively short time limit for access to abortion and a framework for the procedure (interview, etc.) ;

- in the case of a pregnancy that may result in the birth of a malformed or disabled child, the termination of pregnancy is considered to be "normal". With a longer waiting period and less supervision of the procedure.

6.1 Voluntary termination of pregnancy :

In France, an abortion may be carried out before the end of the twelfth week of pregnancy, i.e. before the end of the fourteenth week after the start of the last menstrual period (14 weeks of amenorrhoea). The law allows any pregnant woman who considers herself to be in a situation

of distress to ask a doctor to terminate her pregnancy, whether she is an adult or a minor. Only the woman concerned may make the request. The 2013 Social Security Financing Act provides for 100% reimbursement for voluntary termination of pregnancy. This full reimbursement has been effective since 31 March 2013, and abortion is now fully reimbursed by the health insurance system.

For minors, the psychosocial interview remains compulsory, and parental authorisation is no longer required (accompanied by an adult of the minor's choice), in all cases free of charge for minors, while maintaining the conscience clause. The law reiterates that this is a purely individual prerogative, the exercise of which must under no circumstances constitute an obstacle for the woman, such as to prevent her from having access to an abortion within the legal time limit, which is why article L. 2212-8 of the Public Health Code stipulates that the doctor is now "obliged to inform the interested party without delay of her refusal and to inform her immediately of the names of practitioners likely to carry out this procedure...".

6.2 Termination of pregnancy for medical reasons :

The creation of multidisciplinary centres for prenatal diagnosis means that the diagnosis is made by a team of doctors specialising in foetal medicine, and that the request for an IMG, made by the parents, is signed by two doctors from this centre, who are perfectly identified, and according to a procedure that can be traced and monitored by magistrates and the ABM . It now comprises at least four people: a doctor qualified in gynaecology and obstetrics, who is a member of a multidisciplinary centre for

prenatal diagnosis; a practitioner specialising in the condition from which the woman suffers; a doctor chosen by the woman; and a qualified person bound by professional secrecy, who may be a social worker or psychologist.

When termination of pregnancy is envisaged on the grounds that there is a strong probability that the unborn child will be affected by a particularly serious condition recognised as incurable at the time of diagnosis, and except in the case of a medical emergency, the woman is offered a period of reflection of at least one week before deciding whether to terminate or continue her pregnancy.

7. Organs and cells (organ transplants) :

Law no. 96-654 of 29 July 1994 sets out several major principles that are still valid today: presumed consent of the donor, donation free of charge, anonymity of the donor (and his or

her relatives) for the recipient and vice versa. It also announced the creation of a dedicated public agency, the French Transplant Establishment, to supervise and control organ removal and transplantation activities.

The French Bioethics Act, amended on 7 July 2011, included new provisions in the Public Health Code, such as so-called "cross-donation", which allows a person who has expressed an intention to donate to a waiting recipient to be offered the possibility of cross-donation in the event of medical incompatibility with the initial recipient. The circle of living donors is extended to include any person who can provide proof of a close and stable emotional relationship with the recipient for at least two years.

Article 8 also provides for information on organ donation to be provided in secondary schools and higher education establishments, and article 9 requires the patient's personalised medical record to include information on the legislation relating to organ donation. Article 11 introduces the principle of non-discrimination against donors of elements and products of the human body.

For umbilical cord blood and placental blood, the law prohibits the creation of autologous cord blood and placental blood banks, since collections can only take place in authorised health establishments.

9. Research on human embryos:

The law authorising research on human embryos and embryonic stem cells, subject to conditions, was passed by the national assembly on 16 July 2013, validated by the constitutional council on 1 August, and promulgated by the president of the republic on

6 of the same month. In accordance with the blocked vote procedure set out in Article 44(3) of the Constitution, Article L.2151-5 of the CSP, which previously stated the principle that "research on the human embryo, embryonic stem cells and stem cell lines is prohibited", has been amended. From now on, the principle is that "no research on the human embryo or on embryonic stem cells may be undertaken without authorisation".

The law provides that research may be carried out on supernumerary embryos conceived as part of medically assisted procreation (IVF) that are no longer the subject of a parental project. As with the previous legislation concerning derogations from the prohibition in principle, the present law stipulates that four cumulative conditions must be met in order to obtain authorisation for research on embryos and embryonic stem cells.

The 1st condition of article L. 2151-5 as amended by the present text remains unchanged and stipulates that the scientific relevance of the research must be established. The ABM is responsible for authorising research protocols, after checking that all the legal conditions have been met. The procedure for authorisation of a research protocol by the ABM is also changing, with a view to increasing the ABM's autonomy: the decision to authorise a protocol and the opinion of the Orientation Council no longer have to be substantiated; the ministers responsible for health and research, to whom the decision and opinion are communicated, no longer have the power to prohibit or suspend the implementation of a protocol for failure to comply with the conditions laid down.

Secondly, Article 2 states that "the research, whether fundamental or applied, must have a medical purpose". As the law currently stands, the concept of "major medical progress" is used, replacing the reference made by the 2004 law to major therapeutic progress, which posed problems of application.

In the 3rd clause, the impossibility of "achieving the expected result through research not using human embryos" must be "expressly" established; and in the last clause, "the research project and the conditions for implementing the protocol" must respect the ethical principles relating to research".

Finally, the obligation to inform the couple (from whom the embryos are derived) of the nature of the planned research, to enable them to give free and informed consent, which was included in the 2011 law, disappeared with its revision in 2013.

11. The patentability of living matter (genes and elements of the human body) :

There is a contradiction in the wording of Article 5 of European Directive 98/44/EC, which prohibits in its 1st paragraph the patentability of a gene as a basic constituent of the human body, while authorising in paragraph 2 the patenting of a gene once it has been isolated. The criterion for patentability would thus lie in the treatment of the gene and not in its nature. The human gene has a dual nature. It is both a chemical molecule, patentable like so many others, and an element in a programme of fundamental properties of the human being.

France transposed this directive imperfectly in its bioethics law of 7 August 2004. Without going into the details of Article L611-18 of the French Intellectual Property Code (CPI), these provisions have been incorporated. It should be noted that French law is more restrictive on

protection, since it states that "only an invention constituting the technical application of a function of an element of the human body may be protected by patent" and that "this protection covers the element of the human body only to the extent necessary for the realisation and exploitation of this particular application".

12. End of life :

In France, "death" is governed mainly by two laws: the 2002 law on patients' rights, and the Léonetti law of 22 April 2005 on the rights of patients at the end of life. The law of 22 April 2005, known as the Léonetti law, created or extended several specific means of expressing the patient's wishes, expressed in advance, to doctors.

The general idea is to encourage palliative care, prohibit "active euthanasia" and prevent doctors from practising "unreasonable obstinacy" in caring for patients at the end of their lives. A balance is also sought between avoiding unnecessary suffering for a patient who is considered to be dying and keeping him or her alive.

The establishment of this institution was the first stage in a series of reflections and public debates on the end of life that have been taking place, in various forms, for over two years now . On 18 December 2012, Professor Didier Sicard submitted his report "Thinking in solidarity about the end of life". The conclusions of the Sicard mission call into question the way in which medicine looks at the end of life. They question the responses it tends to provide to the various concerns raised by patients and their families, but the report also challenges society on what it expects from its medicine, on the legislative tools that could be made available to carers to better respond to the difficulties experienced by patients and their relatives.

13. Genetically modified organisms:

The law provides for the creation of the High Council for Biotechnology (composed of a scientific committee and an economic, ethical and social committee), and the introduction of technical coexistence measures aimed at avoiding the presence of traces of GMOs in any other product.

a liability/reparation scheme to provide compensation in the event of contamination of conventional production by GMOs,

the need to define "GMO-free" sectors, and also the offence of mowing.

Article 2 defines the main principles governing the text as a whole: these include prior, independent, transparent, multidisciplinary and impartial assessment and expertise, the principles of precaution, prevention, public information and participation, the freedom to produce and consume with or without GMOs, and the protection of agricultural structures, local ecosystems and "GMO-free" sectors. However interesting these principles may be, they are not necessarily reflected in the rest of the text, introducing uncertainties and inconsistencies.

The current law on GMOs is codified in the Rural Code, the Environmental Code and the Public Health Code. All GMOs are covered by these provisions, with the exception of those obtained by techniques that are not considered by their natural nature to lead to genetic modification, or those that are traditionally used without any proven disadvantage for health or the environment.