Deliberation 2019-097 of July 11, 2019 National Commission for Computing and Liberties Legal status: In force Date of publication on Légifrance: Wednesday July 31, 2019 Deliberation No. 2019-097 of July 11, 2019 providing an opinion on a bill relating to bioethics (request for opinion no. 19011835)The National Commission for Computing and Liberties,Seizure by the Ministry of Solidarity and Health of a request for an opinion concerning a bill relating to bioethics;Given the convention No. 108 of the Council of Europe for the protection of individuals with regard to the automatic processing of personal data; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 relating to the protection of natural persons with regard to the processing of personal data and to the free movement of such data, and repealing Directive 95/46/EC (general regulation on data protection); Having regard to the Civil Code; Having regard to the Code of the public health; Having regard to law n° 78-17 of January 6, 1978 as amended relating to data processing, files and freedoms, in particular its article 8-I-4°-a); Having regard to decree n° 2019-536 of May 29, 2019 taken for the application of law n ° 78-17 of January 6, 1978 relating to data processing, files and freedoms; After having heard Mrs. Valérie PEUGEOT, commissioner, in her report, and Mrs. Nacima BELKACEM, Government Commissioner, in his observations, Issues the following opinion: law no. 78-17 of January 6, 1978 as amended, of a request for an opinion relating to four measures of the bill relating to bioethics (hereafter the bill) falling within the scope of the missions carried out by the Commission. The urgency was invoked by the government, in accordance with the provisions of Article 9-I of Decree No. 2019-536 of May 29, 2019 taken for the application of Law No. 78-17 of January 6, 1978 relating to information technology, files and freedoms. The draft law on bioethics was preceded by opinion 129 on the contribution of the National Consultative Ethics Committee to the revision of the bioethics law of September 18, 2018. A study , in the form of a report entitled Revision of the bioethics law: what options for tomorrow? was also carried out, at the request of the Prime Minister, by the Council of State; it was adopted at a general meeting on June 28, 2018. The four measures of the bill, submitted for examination by the Commission, aim to: determine the framework to be applied to the processing of personal data constituted by the biomedicine and the Commission for access to non-identifying data and the identity of the third-party donor for the purpose of allowing the exercise of the right of access to the origins of the child conceived from a donation of gametes or embryos (articles 3 and 3 bis of the draft); securing the correct information for the patient when algorithmic processing of massive data is used during an act of care (article 11 of the draft); amending the provisions of the law information technology and freedoms concerning the procedures for examining genetic characteristics for scientific research purposes (article 18 of the draft); in particular organizing the secure transmission of the results of genetic

analyzes to the laboratory authorized by the Regional Agency health insurance directly to the prescriber (article 25 of the draft). As a preliminary point, the Commission would like to point out that, without calling into question the legitimacy of the new measures introduced by the bill, sufficient guarantees with regard to respect for the fundamental principles of the right to the protection of personal data must be put in place. work. It considers that suitable legal and technical measures must be provided in order to ensure a high level of data protection. In this context, it makes the following observations: On medically assisted procreation (art. 3 and 3 bis of the bill): Concerning the transmission of personal health data of children conceived for the benefit of donors of gametes: Articles 3 and 3 bis of the bill open up the possibility for a doctor to access non-identifying medical information, in the event of medical necessity, for the benefit of a gamete donor. The government has clarified that the purpose of this device is to allow a doctor, who provides health care for a gamete donor, to contact a doctor from the Center for the Study and Conservation of Eggs and Sperm (CECOS) to obtain information of a medical nature relating to children born from donations which would be useful for the health monitoring of the donor, excluding information likely to identify the child(ren) conceived. Firstly, the Commission indicates that the non-identifying medical information contained in the CECOS files constitutes personal health data in accordance with the provisions of Article 4-15) of the GDPR. It notes that a doctor who requests, under the health monitoring of a donor, the transmission of health data of a child conceived from a donation does not intervene, under Article L. 1110 -4 of the public health code (CSP), as a member of the care team for the conceived child. It also observes, still pursuant to the aforementioned Article L. 1110-4, that the conditions for exchanging and sharing health data are strictly defined and that said data is protected by medical secrecy, except in cases of exceptions expressly provided for by law. It adds that only a legislative measure is likely to render inapplicable the provisions of the Criminal Code relating to the sanctions attached to the disclosure of information protected by medical secrecy. On this basis, it notes that the draft law on bioethics provides a sufficient legal basis for the transmission of personal health data of the child conceived to the doctor of the third-party donor.Secondly, with regard to the notion of non-identifying data, the Commission invites you to refer to the developments below concerning the nature of the data collected. It therefore draws the government's attention to the possible risks of re-identification of the child born from the donation which would result from the transmission of said data. Thirdly, it wonders about the practical methods of implementing these provisions, in particular with regard to the way in which the data will be communicated to the donor from the CECOS databases, as well as whether the children or the holders of parental authority will be informed of the effective access to data concerning the children by the donor, access being able at the very

least to generate interrogations on the state of health of the child. Furthermore, the Commission is wondering about the nature and methods of data collection with regard to the monitoring of the state of health of children from donations by the CECOS. Finally, the Commission notes that Articles 3 and 3 bis of the draft remove the reference to the provisions of the Data Protection Act, which is now being done, with regard to the formalities to be carried out and the powers of the Commission over the processing operations. Since this deletion does not affect the obligation for data controllers to comply with the provisions of the GDPR and the Data Protection Act, this does not call for any particular observation on the part of the Commission.Concerning the processing of personal data compiled for the purpose of exercising the right of access to the origins of children resulting from a donationThe bill on bioethics intends to establish the right, for children conceived through medical assistance to procreation with a third-party donor, to access their majority and their origins as soon as they request it. To this end, it grants the Biomedicine Agency a new competence: that of implementing the processing of personal data, collecting the data necessary for the exercise of this right. It also creates an ad hoc commission, placed under the Minister responsible for health, responsible for managing requests for access to non-identifying data and to the identity of the donor. for a child to have access to his origins and to see himself, consequently, communicate personal data relating to the third-party donor must be distinguished from the right of access of the person concerned to data concerning him as provided for by the provisions of article 15 of the GDPR.On the methods adopted for the processing of personal data transmitted by the CECOS to the Biomedicine Agency, as well as the processing operations set up by this agency and the commission for access to non-identifying data and the identity of the donor for the purpose of allowing access to children conceived at their origins, the bill proposes two distinct orientations corresponding to the scenarios presented respectively in arts icles 3 and 3 bis: Article 3 of the bill states that access to non-identifying data relating to a third-party donor (age, state of health at the time of the donation, physical characteristics, family or professional situation, country of birth, motivations for the donation) and, if the child so wishes, the identity of this third party requires: the express consent of the third party donor to the communication of this data and of his identity (…) collected at the time of his donation . The government has specified that the consent of the third-party donor to the donation entails their consent to the transmission of their non-identifying data and their identity to the adult person conceived by medically assisted procreation who would request them from their majority. The adult can either request only access to non-identifying data, or access to identity, or both. If this drafting option were to be maintained, the Commission requests that the fact, for the donor, of consenting to make a donation entails consent to giving access to his

identity be clearly specified in the draft. Article 3 bis of the draft law provides that access to the non-identifying data of the donor, with the exception of those which would clearly allow his identification, is systematic when the child, having reached the age of majority, requests it. The third-party donor could then object to the collection of non-identifying information relating solely to his family and professional situation, his country of birth and his motivation for the donation. The child could also (…) access the identity of the third-party donor, subject to express consent, at the time of the request (…). The government has also specified that consent to donation implies the consent of the third-party donor to the transmission of this non-identifying data. The Commission notes that the choice of this wording option is likely to create a difference in treatment between children for whom the donor has consented to access to identifying data concerning him and children for whom the donor has not given his consent. .The Commission indicates that, although it is only commenting on the scenarios presented in the bill before it, other options more protective of the rights of the persons concerned could have been considered, in particular by limiting the transmission of data concerning donors to the Biomedicine Agency in cases in which they have consented to their conceived children having access to them. As regards the processing of data whose implementation is planned, the Commission notes that three categories of processing of personal data takes place in the mechanism for access to origins provided for by the project: the processing implemented by each of the CEs COS, whose main purpose is the management of gamete and embryo donations in the context of medically assisted procreation. The transmission of data relating to donors and children conceived to the Biomedicine Agency constitutes a new and ancillary purpose to this processing; the processing implemented by the Biomedicine Agency, the purpose of which is the collection and storage data necessary for access to the origins of children conceived; the processing implemented by the Commission for access to non-identifying data and the identity of the third-party donor, the purpose of which is to manage requests for access to origins .Concerning the legal basis to be retained for the processing of personal data constituted and the formalities to be carried out:Based on the clarifications provided by the government, the Commission notes that Articles 3 and 3 bis of the bill relating to the bioethics require the transmission of data from third-party donors by the CECOS to the Biomedicine Agency and to the commission for access to non-identifying data and the identity of the donor. Commission considers that the processing operations constituted are, according to the current wording of the project, by application of the provisions of Article 6-1-c) of the GDPR, necessary for compliance with a legal obligation, insofar as the data will be transmitted to the Biomedicine Agency in all cases. This observation has the practical consequence that a donor who refuses to have his data transmitted to the Biomedicine Agency, in particular because he does

not want data concerning him to be transmitted to a conceived child, could not make a donation. Thus, the Commission draws the government's attention to the interpretation that could be made of Articles 3 and 3 bis of the draft and which could be different from that made by the government, insofar as it is not expressly indicated that the refusal to transmit non-identifying and identifying information would prevent the completion of a donation. The Commission therefore requests that the draft law be clarified on this point. The Commission also indicates that the processing involved is processing of personal health data falling within the scope of the specific provisions of the Data Protection Act. It recalls in this respect that they will have to be the subject of prior formalities with it. The Commission stresses that it will be necessary to determine whether this processing will have to be authorized in accordance with the provisions of Article 66 III of the Data Protection Act, or of a decree in Council of State issued after consulting justified and published by the Commission in accordance with the combined provisions of articles 6-III and 31-II of the law. The processing implemented by the data access commission must also be subject to prior formalities.Concerning the nature of the data collected: Articles 3 and 3 bis of the draft provide that children conceived by medically assisted procreation with third-party donors can access non-identifying data relating to this third party (age, state of health at the time of the donation, physical characteristics, family or professional situation, country of birth, reasons for the donation). Firstly, with regard to the exact nature of the non-identifying data, the Commission points out that the age, the state of health of the donors at the time of the donation, the physical characteristics, the family or professional situation, the country of birth , the motivations for donation of third-party donors constitute, within the meaning of the GDPR and the guidelines of the Article 29 Data Protection Working Party (G29), personal data relating to identifiable natural persons. In this respect, it specifies that the G29, in its opinion 05/2014 of April 10, 2014 on anonymization techniques (hereinafter referred to as G29 guidelines), retains that data processing is a priori anonymous when that it is not possible to individualize, correlate or interfere with the data. The Commission observes in this case that there are, from these data, possible risks of re-identification of third parties donors. It therefore draws the government's attention to the risk of misinterpretation that could result from the use of these terms if it were to prove that the non-identifying data allow re-identification of the persons concerned. It therefore proposes retaining wording specifying that the data is likely to be indirectly identifying and that the donors are clearly informed of this. Furthermore, the Commission draws the government's attention to the meaning to be given to the notion of donation, as provided for by the provisions of article L1211-5 of the CSP. The Commission considers that this principle, which until now prohibited children from having access to the identity and indirectly identifying data of the donor, is in the state of the bill called

into question, insofar as the transmission of personal data to conceived children would be binding on any donor. It also questions the advisability of maintaining the reference to this principle in Articles 3 and 3 bis of the bill and suggests that the government provide the necessary clarifications on the relationship between the principle of anonymity of donation and the right of access to origins.Secondly, with regard to the scope of the collection of indirectly identifying data, the Commission recalls that under the principle of data minimization provided for in Article 5-1- c) of the GDPR, personal data must be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed. The Commission notes that the draft law draws up an exhaustive list of indirectly identifying data, transmitted by the CECOS to the Biomedicine Agency for the purpose of exercising the right of access to origins. It notes that only Article 3 bis provides for the third-party donor the option of opposing the collection of the following data: his family and professional situation, his country of birth, the reasons for his donation. In view of these elements, without question the legitimacy of access to origins, the Commission wonders about the consequences that the discovery, for a child, of certain information concerning the donor could have (such as a serious pathology discovered later, for example), and thereby on the relevance, adequacy and potentially excessive nature of the transmission and collection of certain indirectly identifying data, in particular health data, with regard to the precise purpose of accessing one's personal origins. In this respect, in application of the principle of data minimization provided for in Article 5-1-c of the GDPR, the Commission invites the government to specify, within the framework of the aforementioned implementing decree, the exact nature of the data processed and transmitted to the Biomedicine Agency. On the data retention period The draft provides for a minimum data retention period of eighty years, a period which will be set by decree in the Council of State. The government has justified this period of minimum storage on the basis of the following three reasons: the gametes of a donor can be used about ten years after the donation; the child resulting from the donation must be of age to request access to his or her origins; the adult child can initiate this process at any age. The Commission recalls that personal data must be kept for a limited period of time to meet the purposes of the processing in accordance with the provisions of Article 5-1-e) of the GDPR. It therefore asks, unless the law refers on this point to its implementing decree, that the draft itself provide for a maximum duration and not a minimum duration for the retention of data. Furthermore, the Commission suggests that hypotheses in which the storage period could be reduced are provided for, for example when all the children from the same donor have exercised their right of access to their origins or when no use has been made of the donated gametes. On information and procedures for exercising the rights of individualsThe Commission recalls that data

controllers must ensure the effective implementation of the rights of data subjects (third-party donor, child), provided for in the provisions of Articles 12 to 23 GDPR (right to information, right of access, rectification and restriction of processing). More specifically, with regard to the right to information of third-party donors mentioned in Article 13 of the GDPR and by application of the principle of transparency referred to in Article 12 of the GDPR, the Commission considers that third-party donors must be expressly informed the possible transmission, to the majority of children conceived and for those who request it, of indirectly identifying data collected concerning them as well as, where applicable, identification data. It would like this information to be provided prior to the collection of data and the donation. With regard to Article 3 bis of the bill, the Commission requests that the provision provided for in terms of information be supplemented in the bill: the donor should be expressly informed that consent to the donation entails consent to the transmission of his indirectly identifying data; the information should also cover the risks of re-identification in the context of the transmission of indirectly identifying data. the Commission points out that if the processing envisaged were to be based on compliance with a legal obligation, as the draft seems to provide, third-party donors will be deprived of the exercise of their right to object referred to in Article 21 of the GDPR . It also expresses the wish that the law expressly provides that the donor will be informed that his data will necessarily be processed in the context of the implementation of the right of access to origins if the current wording had to be maintained. The procedures according to which this information will be issued must also be specified in the aforementioned decree. On data security As the processing operations concerned are likely to create a high risk for the rights and freedoms of natural persons, the Commission finally recalls that an analysis impact on data protection must be carried out by data controllers in application of the provisions of Article 35 of the GDPR.On the provisions relating to the algorithmic processing of health data (Article 11 of the bill)Article 11 of the draft inserts a new article L.4001-1 into the public health code relating to the guarantees provided in the event of recourse to algorithmic processing of massive data by a health professional. of the concept of massive data processing used for the purpose of ruling on the individual situation of a patient. In fact, massive processing takes place upstream of individual care in order to identify rules that will then be applied during the care of a patient whose data will be submitted to the system. Thus, it is more the product of the processing of massive data that is used in support of the medical act. informed of the use of algorithmic processing of massive data and the methods of action of this processing. On this point, the government has clarified that the information of the persons covered would occur when the results are delivered, and not prior to the use of the treatment. Although the introduction into the law of such provisions constitutes a significant advance and which must be

underlined, the Commission wishes to draw the government's attention to the need to preserve the full scope of the principles laid down in particular by the provisions of Articles L. 1111-2 and L. 1111-4 of the CSP according to which the patient has the right to be informed about his state of health and the treatments offered to him, and take decisions concerning his health with the health professional and taking into account the information and recommendations he provides. therefore that the use of such treatment be the subject of information prior to its use by the healthcare professional. On the communication of the results, the Commission recommends that the drafting of the bill clearly distinguishes the raw result resulting from the algorithm from the assessment and decision of the healthcare professional in the context of patient care. This distinction would make it possible to guarantee, on the one hand, the access of the person concerned to all the information concerning him and, on the other hand, the principles of independence and freedom of prescription of the health professional. It is also a measure which aims to guarantee that the medical decision is not based exclusively on automated data processing in accordance with the provisions of Articles 22 of the GDPR and 47 of the Data Protection Act. On the configuration of the algorithmic processing, the Commission wonders about the precise role of the health professional on such a device, the nature of the modifications that he could bring to it (choice of massive data, options for processing patient data?) and the consequences that could result both for him (implying his liability) and for the patient (in the event of an error or malfunction, for example). The Commission considers that these provisions can be interpreted in two ways. The first interpretation, which would not raise any particular difficulty, would be to consider that it is for the healthcare professional to enter the individual data of the patient for whom he provides care in the tool implementing an algorithmic processing , in order to obtain a result. The second hypothesis would consist in allowing the healthcare professional to modify the algorithmic processing itself. In this second hypothesis, the Commission considers that such a practice should be framed more precisely, insofar as not all health professionals have the technical skills necessary for such interventions. The Commission therefore suggests that the government clarify the project in order to that it be specified whether the healthcare professional referred to in II of draft article L. 4001-1 of the CSP is the professional involved in the care of the patient or a professional carrying out his duties on behalf of the treatment provider algorithmic as well as on the meaning to be given to the term parameterization. In this context, she also wonders whether human intervention on the parameterization of algorithmic processing could not rather relate, not to each individual decision, but to series of decisions. This supervision could thus take the form of a human and contradictory deliberation, with the creation, for example, of a medical college (at the level of the structure which deploys the system) which would supervise and

support the overall use of the algorithm. , by examining and questioning its configuration but also all the effects – direct and indirect – of the system. In addition, the Commission draws the government's attention to the absence of scientific evaluation of such treatments, apart from those currently planned. in the context of CE marking prior to the placing on the market of medical devices and which could appear insufficient with regard to the assessment of the effectiveness of the product concerned. On this point, the Commission notes that an algorithmic processing massive data used by a healthcare professional in the context of carrying out preventive, prognostic, diagnostic or therapeutic procedures, as is the case with diagnostic, decision-making or prescription assistance software could be similar to a medical device, as defined by the provisions of Articles L. 5211-1 et seq. of the CSP and the case law established by the CJEU in its decision of December 7, 2017 (C□329/16, December 7, 2017) and taken up by the Council of State. It therefore recommends that an assessment of the scientific interest and the relevance of the results offered by these treatments be systematically planned and prior to their use in the context of preventive, prognostic, diagnostic or therapeutic procedures. In its last observations, the government indicated that the concept of algorithmic processing refers to three cases: cases covered by I of text would be diagnostic applications and those covered by II and III implantable medical devices (eg artificial pancreas, hip prosthesis, breast implant, etc.). The government added that other forms of artificial intelligence (AI) are not excluded from the scope of future article L. 4001-1 of the CSP without specifying whether or not they were medical devices. The Commission notes that, while the answers provided by the government on the configuration of the algorithm by the health professional, its evaluation, the consequences on liability, are clear with regard to medical devices as such and do not raise new difficulties with regard to what is already implemented in practice, such is not the case for other forms of AI for which the Commission insists on the need to define a dedicated legal framework. Consequently and with regard to all of these elements, the Commission suggests that it be expressly stated in the text that the treatments mentioned come under the legislation applicable to medical devices. This clarification would thus make it possible to exclude from the scope of the text processing operations for which it defines neither the nature nor the applicable legal regime. , in the absence of validation of such a practice by the High Authority for Health (HAS), whose mission is in particular to recommend good practices to health professionals. In such cases, their use should then intervene in the compliance with the provisions of the public health code applicable to research involving the human person and the provisions relating to research, studies and evaluations in the field of health provided for in articles 72 and following of the data protection act. On the examination of genetic characteristics for the purposes of scientific research (art. 18

of the bill) Article 18 of the bill provides for amendments to the provisions of the CSP and the Data Protection Act. As a preliminary point, the Commission recalls that the GDPR, in its article 9, included genetic data in the category of data whose processing is in principle prohibited and can only take place under the conditions exhaustively listed by this same article, as well as by the law of the Member States of the European Union. The Commission also recalls that the samples taken from elements and products of the human body constitute, by their nature, sources of data which could be qualified as inexhaustible, with regard to the constant evolution of analytical techniques. The conditions for their storage and use must therefore be particularly rigorous and respectful of individual rights. that many researchers encountered difficulties in informing the people concerned in the context of projects requiring the reuse of biological samples, but also of data. In this context, particularly with regard to public research projects, the lack of human and financial resources is regularly invoked to justify the impossibility of informing people. It therefore suggests that a reflection be carried out, not to create derogations from the obligation to inform, but to find solutions aimed at enabling researchers to carry out their missions under conditions favorable to respect for the rights of people whose data and/or samples are reused. On this point, the Commission refers, for example, to the mechanism put in place within the framework of the reference methodology 004 (MR 004) by which the persons concerned can consult the research projects implemented by means of a dedicated website. , of which they have been individually informed beforehand.On the updating of the provisions resulting from the current article L. 1131-1-1 of the CSP (draft article L. 1130-5 of the CSP)Article L.1131 -1-1 of the CSP, introduced by law n° 2012-300 of March 5, 2012 relating to research involving the human person, establishes a derogation from the principle of the obligation to obtain express and written consent to the examination of genetic characteristics (article 16-10 of the civil code), when it is carried out for the purposes of scientific research. Thus, such an examination can be carried out on the basis of information and provided that the person concerned does not oppose it. If the person concerned cannot be found, a committee for the protection of persons, as provided for in article 1123-7 of the CSP, may give an opinion in favor of carrying out this examination. Whereas the spirit of the current provisions (which provide that this article does not apply to research whose results are likely to allow the anonymity of the persons concerned to be lifted) as well as the interpretation made of it by the Council of State in its study in 2009 on the revision of the bioethics laws, seem to be to exclude from this mechanism derogating from consent genetic examinations presenting a high risk of re-identification, the Commission notes that the wording of the last paragraph of draft article L. 1130-5 of the CSP would now allow researchers to carry out any type of genetic examination (including, for example, complete

genome sequencing) on the sole condition that the publication relating to the research does not present te only anonymous results. This analysis has been confirmed by the government. At a time when recourse to this type of examination is becoming increasingly easy and tending to become commonplace, both in the context of care and research projects, the Commission warns now on the proliferation of databases used and reused, in particular for public and private research purposes, which already contain genetic data from increasingly comprehensive examinations and concerning an exponential number of people . Considering also the many genetic databases created in the context of commercial sequencing and genetic data sharing services for individuals, and without going into the demonstration of the illegality of such activities at national level, the Commission notes that genetic data can no longer be considered anonymous today and that data from complete sequencing also presents a high risk of re-identification. The Commission is therefore concerned about a reduction in the guarantees of the rights of individuals, in the absence of explicit consent, or even information from the people, even if a committee for the protection of people is consulted in the latter case. In this respect, it requests that appropriate guarantees be provided for by the texts, in particular in terms of informing people and exercising their rights, which it will have the opportunity to measure in the context of the opinion it will deliver on the draft decree and of which it must be seized, pursuant to Article 8-I-4°-a) of the Data Protection Act and which will set the conditions for the application of these provisions. The Commission recalls that this derogation from the principle provided for by the legislator of the collection of express consent from the persons concerned during an examination of genetic characteristics should be exceptional. 'a request for authorization from it, in application of the provisions of articles 72 and following of the amended Data Protection Act. The Commission notes that the project provides for the addition of the definition of the research program. It notes that the latter will be limited to research in a specific scientific field. However, while the current provisions provide that the person is informed of the research project, this person would now only be informed of the research program, within the framework of which a multitude of research projects could be carried out, both by public actors than private. The Commission therefore wonders about the articulation of these provisions with those of the Data Protection Act which provide, in addition to general information, an obligation to provide individual information to the persons concerned, which applies for each processing of Furthermore, the Commission notes that the draft article provides that the right to object to the examination may be expressed informally as long as there has been no manipulation of the element concerned due to research.Questioned by the services of the Commission, the government indicated that this right of opposition related specifically to carrying out the examination of the genetic characteristics of individuals and not to the

processing of data associated with the sample or produced subsequently after its to analyse. In this respect, the Commission therefore wishes to recall that the right to object provided for in Article 21 of the GDPR as well as the right to erasure provided for in Article 17 of the GDPR are applicable under the conditions provided for by the GDPR, and this, even after manipulation. It asks that details be provided in this regard in the draft. Finally, the draft specifies the situations in which, in the event of a lack of information from the persons, the research requires the opinion of a CPP. In addition to people who have died or lost sight of, the hypothesis of a person unable to express their will is mentioned. The Commission wonders about the advisability in this last case of delivering the information to the trustworthy person, to the family or to the relatives, as defined in the last paragraph of the current article L. 1131-1 of the CSP. On the draft article 75 of the Data Protection Act The draft seems to imply that the express consent of the person to the processing of data must be obtained in addition to that required for carrying out the examination of his genetic characteristics. , it seems that there is confusion between the consent to carry out the examination of genetic characteristics (articles 16-10 of the civil code and L 1131-1 of the CSP) and the consent to participate in research (article L1122- 1-1 of the CSP). The Commission generally considers that the express consent of individuals should be obtained prior to carrying out an examination of genetic characteristics, whether it is carried out within the framework of health care or within the framework of a research, apart from the case provided for in article L. 1131-1-1 of the CSP (draft article L. 1130-5 of the CSP). The Commission draws the government's attention to the fact that the proposed wording could be interpreted as an obligation to obtain the express consent of the person concerned in the event of the reuse of test results, which could for example appear in their medical file. However, it considers that the reuse of results of examination of genetic characteristics obtained in the context of healthcare does not require obtaining the express consent of the person concerned. The person must however be informed and must be able to oppose it. Moreover, the proposed wording rightly dissociates the right of opposition to participate in research and the right of opposition to the processing of their data. However, the Commission would like to point out that the fact that a person objects to taking part in a research project should de facto entail a ban on processing the data of the person concerned. In order to clarify these provisions, the Commission proposes to the government the following wording: In the event that the research requires carrying out an examination of genetic characteristics, the informed and express consent of the persons concerned must be obtained prior to carrying out the examination. This article does not apply to research carried out pursuant to Article L. 1130-5 of the Public Health Code. On the examination of genetic characteristics for health care purposes (art. 25 of the draft of law)Article 25 of the draft provides for

several amendments to the Public Health Code:Updating the title of Chapter I of Title III of Book I of the first part of the Public Health CodeThe draft provides for replace the current title General principles with the following title: Information of relatives and procedures for carrying out examinations of genetic characteristics. The Commission understands, following the observations of the government, that the term information of relatives refers to the information of the members of the family potentially concerned by the diagnosis of a genetic anomaly in a person, in accordance with the provisions of Article L 1131-1-2 of the public health code. The government specifies on this point that kinship includes relatives of the first degree (parents, children, brothers and sisters), even of the second degree (grandchildren, grandparents, uncles, aunts, nephews, nieces), even of degree higher. The Commission is wondering about the interpretation of the mention of information on relatives in the title of Chapter I. As the texts currently stand, the person of trust or a relative of the person concerned are also persons who may be affected by the information mentioned in the title of Chapter I (current article L.1131-1, paragraph 2 of the CSP). During the exchanges which took place with the services of the Commission, the government indicated that a modification of the current article L.1131-1 of the CSP, of which the Commission regrets not having been seized, was also planned. Thus, the Commission notes that the draft provides, in a new article L.1130-3 of the CSP, that by way of derogation from article 16-10 of the civil code, when the person is unable to express his consent, the examination or identification may be undertaken for medical purposes in the interest of that person. Prior to carrying out the examination, the doctor ensures that she has not previously objected to it with the trusted person mentioned in article L. 1111-6 of the CSP, the family or, default, of a relative or, where applicable, of the person in charge of a legal measure for the protection of the person. As a result, the proposed modification replaces the prior consultation of the person of trust, the family or one of the relatives of the person concerned, in the event that it is impossible to obtain the consent of the person concerned for the realization of an examination of his genetic characteristics, by verification by the doctor, with the persons previously concerned and with the person in charge of a legal protection measure, that the person concerned has not previously opposed the carrying out of a Therefore, the Commission wonders: on the one hand, about the reasons for the suppression of the prior information delivered to the persons covered by the draft article L.1130-3 of the CSP relating to the realization of an examination of the genetic characteristics of the person concerned who is unable to express his consent; and, on the other hand, on the hypotheses in which a person concerned could have pronounced his opposition in advance to carrying out an examination of genetic characteristics, whereas Article 16-10 of the Civil Code provides that the express consent of the person must be obtained

beforehand; on the mention of kinship in the title of Chapter I, which no longer seems to correspond to the persons covered by the draft articles L. 1130-1 and L. 1130-3 of the CSP. The Commission requests that the draft be clarified on these points. On the modification of article L 1131-1 -3 of the CSPThe project plans to modify the recipients of the results of the examinations of genetic characteristics. In addition to the person concerned, the recipients of the results would therefore no longer be, where applicable, those referred to in the current article L. 1131-1 of the CSP, but the representative in personal matters of the person. This amendment calls for the following observations: With regard to the terms representative in personal matters of the person, the Commission wonders about the persons referred to by this designation. The government having clarified, during the exchanges which took place with the services of the Commission, that these terms must be understood as the representative of a protected adult within the meaning of Article 459, paragraph 2 of the Civil Code. The government specifies on this point that the representative of a protected adult is the person authorized by the judge to represent a protected adult (article 494-1 and following of the Civil Code), or the guardian when the judge has given them power of representation, but also the mandatary in the case of an active future protection mandate). Therefore, the Commission recommends that reference be made to these provisions in the draft. With regard to the terms, if any, the Commission wonders about the hypotheses in which the results of the examination of genetic characteristics, would be likely to be communicated by the prescribing physician to the person's personal representative. The government specified, during the exchanges which took place with the services of the Commission, that the representative in personal matters of the person is informed of the results of the examination of the genetic characteristics of the person concerned, when the law specifically provides that the protected person must be represented for the decisions or acts relating to his person. The provisions of the current article L.1131-1-3 of the CSP refer today to the transmission, if necessary, to the persons mentioned in the paragraph of article L. 1131-1 of the CSP, which provide that (…) when it is impossible to obtain the consent of this person or, where applicable, to consult the trusted person mentioned in article L. 1111-6, the family or, failing that, one of their relatives, the examination or identification may be undertaken for medical purposes, in the interest of the person . Thus, the provisions currently in force seem to determine both the recipients of the results of the examinations, but also the cases in which the results can be transmitted to them: when it is impossible to obtain the consent of the person. proposed modification: seems to have the consequence, when the person is unable to express his consent, to restrict the field of persons having access to the results of the analyses, which today extends to the persons referred to in Article L 1131-1 paragraph 2 of the CSP (person of trust, family, relatives), while

the latter will de facto be aware of the performance of such an examination; does not make it possible to determine in which cases the representative in personal matters of the person is the recipient of the results of the examination; could create an inconsistency between the person referred to by the term personal representative of the person receiving the results (new article L.1131-1-3 of the CSP), and the person referred to by the term the person in charge of a legal measure for the protection of the person (new article L.1130-3 of the CSP) requested by the doctor prior to the carrying out an examination of the genetic characteristics, if it were to prove that these expressions do not refer to the same people. The Commission therefore requests that the draft be clarified on these points. On the creation of Article L. 2131- 1-1 of the CSP The Commission also notes that draft article L 1131-1-3-II of the CSP provides that the result of an examination of the genetic characteristics of a person will not be transmitted, if necessary, to the medical biology laboratory involved in the transmission of the sample. On the other hand, it retains that the latter will be informed of the communication of the result of the examination to the prescribing doctor by the authorized laboratory. The Deputy Vice-President Sophie LAMBREMON