

DELIBERATION n°2018-297 of JULY 19, 2018National Commission for Computing and LibertiesLegal status: In force Date of publication on Légifrance: Tuesday October 23, 2018Deliberation n° 2018-297 of July 19, 2018 on a single decision authorizing the Lorraine Perinatal Network ( RPL) to implement automated processing for research, study and evaluation purposes requiring access to national data from the program for the medicalization of information systems (PMSI)(Request no. 918186)The National Commission for information technology and freedoms,Registration by the Lorraine Perinatal Network of a request for a single decision with a view to authorizing automated processing for research, study and evaluation purposes requiring access to the PMSI; Convention No. 108 of the Council of Europe for the protection of individuals with regard to automatic processing of personal data; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC; Having regard to the Public Health Code, in particular its articles L. 6113-7 and L. 6113-8; Considering the modified law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms, in particular its articles 8-II-8°, 54, 61 and following; Having regard to law n° 2016-41 of January 26, 2016 on the modernization of our health system, in particular its article 193; Considering the decree n° 2005-1309 of October 20, 2005 modified taken for the application of the law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; Considering the decree n° 98-899 of October 9, 1998 amending Title I of Book VII of the Public Health Code and relating to public and private health establishments practicing obstetrics, neonatology or neonatal resuscitation; Having regard to Decree No. 98-900 of October 9, 1998 relating to the technical operating conditions that health establishments must meet to be authorized to practice obstetrics, neonatology or neonatal resuscitation activities and amending the Public Health Code; Considering Decree No. 2016-1871 of December 26 2016 relating to the processing of personal data called "National Health Data System" Considering the decree of March 22, 2017 relating to the security reference system applicable to the National Health Data System; Having regard to instruction no. DGS/PF3/R3/DGS/MC1/2015/227 of July 3, 2015 relating to the updating and harmonization of the missions of perinatal health networks within a regional framework; of the Expert Committee for research, studies and assessments in the field of health of May 18, 2018; After hearing Mrs. Marie-France MAZARS, commissioner, in her report, and Mrs. Nacima BELKACEM, government commissioner, in its observations, Makes the following observations: The National Commission for Computing and Liberties (hereinafter "the Commission") was seized on May 28, 2018 by the Lorraine Perinatal Network (hereinafter "RPL"), acting in quality of data controller, of a request for

authorization to access data from the program for the medicalization of information systems (hereinafter "PMSI") via the platform of the Agence technique de l'information sur l'hospitalization (hereinafter "ATIH"). Two decrees of October 9, 1998 organize the regionalization of perinatal care and provide for the creation of perinatal health networks (hereinafter "the networks") to ensure territorial coordination between establishments and the various perinatal actors. The instruction of July 3, 2015 relating in particular to the missions of the networks specifies that the latter contribute to the implementation of both regional and national policy in perinatal health and that they provide their expertise to the regional health agencies (hereinafter "ARS"). To do this, the networks collect, produce and analyze perinatal health indicators every year. As part of the management of the networks, a certain number of common tracer indicators, calculated by ATIH from PMSI data, are thus monitored by the networks (multiple births, maternal age, prematurity, stillbirth, etc.). The performance of these missions involves the implementation of numerous processing of PMSI data intended for the evaluation of perinatal health indicators.

devaluation. The Commission considered it appropriate, in view of the elements presented in the application file, to authorize the implementation of this processing on the basis of the provisions of Articles 54-IV and 61 et seq. of Law No. 78-17 of the January 6, 1978 as amended (hereinafter the "Informatique et Libertés" law), as part of a single decision. On the application of the provisions related to the SNDS: Since the PMSI data comes from a component of the National Health Data System (hereinafter "SNDS"), the Commission recalls that all the legislative and regulatory provisions relating to the SNDS are applicable in this case and in particular: The prohibition on using this data for the purposes described in Article L. 1461-1 V of the Public Health Code (hereinafter "CSP"); Compliance with the safety baseline applicable to the SNDS, set by the decree of March 22, 2017; The principle of transparency provided for in article L.1461-3 of the CSP: transmission of the protocol, the declaration of interest and the results to the National Institute for Health Data (hereinafter "INDS"). On the legality of the treatment: The perinatal health networks contribute to "the implementation of the national and regional policy in perinatal health" according to the aforementioned 2015 instruction. The processing operations concerned are intended to allow the evaluation of the perinatal health policy. Given the missions of the networks, the processing operations are necessary for the performance of a mission of public interest and are, as such, lawful with regard to of Article 6, paragraph 1 point e) of the General Data Protection Regulation (hereinafter "GDPR"). On the purpose of the processing and its character of public interest: Processing requiring access to PMSI data are intended to carry out monitoring and evaluation of the perinatal health policy and to carry out studies aimed at monitoring perinatal health indicators, thanks to: an analysis of the supply of care and

hospital flows (ci -after "the studies"); a study of the paths of mother/child patients; an evaluation of practices; an implementation of indicators and relevance of care; an evaluation of PMSI coding. The Commission considers that the purpose of the processing is determined, explicit and legitimate, in accordance with Article 5 paragraph 1 point b) of the GDPR. In addition, it considers that the processing has a purpose of public interest, in accordance with Article 54 I of the "IT and freedoms" law. On the categories of data processed: The Commission recalls that the data controller must only process, for each of the processing operations implemented within the framework of this single decision, the data strictly necessary and relevant with regard to the objectives of the processing operations. The categories of personal data that may be processed are centralized data made available on ATIH's secure platform, in particular on all files in the fields: medicine, surgery, obstetrics and odontology (MCO); follow-up and rehabilitation care (SSR); home hospitalization (HAD). Individual chaining and "mother-child" chaining will be carried out using the "ANO" file. The treatments included as part of the decision unique relate to national PMSI data whose maximum historical depth is nine years plus the current year. The adequacy, relevance and limited to what is necessary with regard to the purposes for which the data are processed, the geographical area concerned and the historical depth of the data consulted must be justified for each processing operation implemented within the framework of this decision. unique in the register of processing activities provided for in Article 30 of the GDPR. On the data retention period: PMSI personal data cannot be stored outside the secure platform by the controller, their export being prohibited. Only anonymous results can be exported. The duration of access to data in the secure platform must be limited to the duration necessary for the implementation of the processing. When the data controller justifies it, access to the data may be maintained at the end of the study, within the limit of two years from the last publication relating to the results. On the publication of the results: The Commission recalls that, in accordance with the provisions of the "Informatique et Libertés" law, the presentation of the results of the data processing cannot in any case allow the direct or indirect identification of the persons concerned. On the categories of data recipients: Only the person responsible for the processing and the persons authorized by it have access to the data within the framework of this single decision. It keeps up-to-date documents indicating the competent person(s) within it to issue the authorization to access the data, the list of persons authorized to access this data, their respective access profiles and the methods of attribution, authorization management and control. These categories of persons are subject to professional secrecy under the conditions defined by Articles 226-13 and 226-14 of the Criminal Code. The qualification of authorized persons and their access rights must be regularly reassessed, in accordance with the methods described in the

procedure. of authorization established by the data controller. On information and the rights of persons: The information of the persons concerned, as to the possible reuse of their data and the methods of exercising their rights, is ensured by a statement appearing on the website of the data controller, health insurance organizations and on media allowing it to be brought to the attention of individuals, in particular posters in premises open to the public or documents given to them. access, rectification and opposition are exercised with the director of the organization managing the compulsory health insurance scheme to which the person rsonne is attached, in accordance with the provisions of Article R. 1461-9 of the CSP. On data security and traceability of actions: The implementation of personal data processing occurring within the framework of the study s is carried out under the responsibility of the data controller, including with third parties acting on its behalf, in compliance with the provisions of Articles 24, 25, 28, 32 to 35 of the GDPR as well as the decree of March 22, 2017 relating to the security baseline applicable to the SNDS. ATIH makes the data available on a secure and approved platform within the meaning of the decree of March 22, 2017 relating to the security baseline applicable to the SNDS. It is based on a secure internet connection (HTTPS protocol) and strong authentication (one-time password generated by a token). Access traceability is ensured and a computer monitoring mechanism records all actions performed by the user. A workspace on the platform is provided by ATIH so that users can consult the data. Only aggregated statistics in such a way that the direct or indirect identification of people is impossible can be extracted from the platform. A copy of all data output is kept by ATIH, which reserves the right to report to the Commission if it becomes aware of information likely to reveal serious shortcomings. Principle of transparency: The provision of data from the NSDS and its components is designed to account for their use to civil society. To this end, Article L. 1461-3 of the CSP makes access to data from the SNDS and its components subject to the communication to the INDS of several elements by the data controller, before and after the studies. Thus, the data controller undertakes to register the studies carried out within the framework of this single decision with the public directory kept by the INDS. This registration, to be carried out by the data controller or the person acting on his behalf, before the start of the processing, is accompanied by the transmission to the INDS of a file comprising: the protocol, including the justification of the interest public, as well as a summary, according to the model made available by the INDS; the declaration of interests of the controller, in relation to the purpose of the processing. At the end of the studies, the method and the results obtained must be communicated to the INDS for publication. The recording of the treatment and the transmission of the results are carried out in accordance with the procedures defined by the INDS. AUTHORIZES, in accordance with this deliberation, the Lorraine Perinatal Network to

implement the aforementioned treatments for a period of six years. The President I. FALQUE-PIERROTIN