

Deliberation 2019-143 of December 5, 2019 National Commission for Computing and Liberties Nature of the deliberation:

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2019-143 of December 5, 2019 providing an opinion on a draft decree amending decree no. 2019-536 of May 29, 2019 taken for the application of law no. 78-17 of January 6, 1978 relating to data processing, files and freedoms (request for opinion no. ° 19017990) The National Commission for Computing and Liberties,

Seizure by the Ministry of Solidarity and Health, the Ministry of Labor and the Ministry of Action and Public Accounts of a request for an opinion concerning a draft decree amending the decree issued for the application of Law no. ° 78-17 of January 6, 1978 relating to data processing, files and freedoms;

Having regard to 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;

Considering the law n° 78-17 of January 6, 1978 modified relating to data processing, files and freedoms and in particular its article 8-I-4°-a;

Having regard to Law No. 2019-774 of July 24, 2019 relating to the organization and transformation of the health system;

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 of Mrs.

Nacima BELKACEM, Government Commissioner, in her observations, Issuing the following opinion: The purpose of this draft decree is to modify decree no. 2019-774 of July 24, 2019 relating to the organization and transformation of the health system.

It calls for the following observations from the commission. On the content of the referral file provided for in article 89 of the decree: In order to facilitate the examination of applications for authorization within the time limits set by law, the commission proposes complete the list of documents making up the authorization application file submitted to the single secretariat so that it also includes: - where applicable, the answers sent by the data controller following the opinion issued by the ethics committee and scientist for research, studies and assessments in the field of health (CESREES) when the opinion rendered is

favorable with recommendations, reserved or unfavourable;

- where applicable, the joint processing responsibility contract in accordance with Article 26 of the General Data Protection Regulation. , namely: - opinions given previously by scientific or ethical bodies . On this point, the commission proposes that it also include, where appropriate, the opinion of the committee set up by the data controller of the health data warehouse in order to assess research projects, studies or evaluations in the field of health, when the project aims to reuse data from this warehouse;

- where applicable, the list of processing operations meeting the characteristics provided for in IV of article 66 of the law of January 6, 1978 referred to above. The file specifies, in this case, the categories of data, the recipients or the categories of recipients. The commission proposes that the application file also include the justification for the use of the single decision mechanism in order to allow it to assess the appropriateness of it;

- with regard to the information of the persons concerned, article 89 of the decree of May 29, 2019 specifies that the file submitted must include, if necessary, the information measures provided for in application of regulation (EU) 2016 /679 of April 27, 2016 referred to above and in Article 58 of the law of January 6, 1978 referred to above, as well as the justification of any request for derogation from this information obligation. The committee proposes to modify this provision so that the file includes the information measures provided for in application of article 69 of the data protection act as well as:

- where applicable, the justification for the exception to the provision of individual information and the appropriate measures implemented by the controller pursuant to Article 14, 5, b of the General Data Protection Regulation ;

- where applicable, the justification for the derogation from information and the procedures for exercising rights by holders of parental authority in application of Article 70 of the Data Protection Act. On the operation and missions of the CESREES:On the opinion of the CESREES on the character of public interest:The draft article 90 of the decree sets the missions devolved to the CESREES which will decide in particular, if necessary, on the character of public interest that the research presents , study or evaluation, thus taking up one of the powers attributed to the National Institute for Health Data by law no. 2016-41 of January 26, 2016 on the modernization of our health system.

It appears from the wording of this draft article that CESREEE, which will examine all the files that will be submitted to the single secretariat, will not systematically rule on the public interest nature presented by the purpose of the processing considered. However, the committee considers it necessary for CESREEE to systematically rule on whether or not a research

project is in the public interest.

In the event that this proposal is not retained, it questions, on the one hand, the criteria that will be implemented by CESREEE in order to trigger an internal referral and, on the other hand, the consistency of the system stipulating that the commission may refer the matter to CESREEE even though the committee has not deemed it appropriate to self-refer during the initial examination of the application file.

She therefore asks for clarification on these points.

The commission's ability to refer matters to CESREEE on matters of public interest is justified by the fact that the examination of research involving the human person falls within the competence of the committees for the protection of persons.

The committee proposes that paragraph 5 of draft article 90 relating to the time limit available to CESREEE to make a decision expressly mentions that the one-month time limit is applicable when it is referred to by the committee. Indeed, there is an ambiguity on this point since the first paragraph of this article only mentions the hypothesis of a referral by the single secretariat, and not that, however provided for by article 72 paragraph 2 of the law of January 6, 1978, of a referral on the initiative of the commission. The latter draws the Ministry's attention to the legal deadlines available to it to make a decision; the requests for which the commission would refer to CESREEE on the public interest are thus likely to be deemed accepted as soon as the opinion is issued, in the absence of suspension of the investigation period in the event of a referral on the public interest.

Finally, the commission suggests that the ministry modify the draft decree so that the applicant is also the recipient of the committee's opinion, as the text currently provides for with regard to the opinion of the National Institute for Health Data. On the reasoning of the opinions of the CESREEEs: The draft article 90 of the decree provides that the opinion delivered by the CESREEEs is reasoned while the draft article 95 mentions a reasoning of the opinion only when the latter is favorable with recommendations , reserved or unfavorable .

In this respect, the commission draws the attention of the ministry to the need for each of the opinions issued by CESREEE to be reasoned, including favorable opinions, and this on each of the points falling within its competence. It considers it desirable in particular that the opinion on the public interest be supported with regard to the body of indices released by the National Institute of Health Data, more particularly concerning the transparency of the results envisaged by the data controller.

The committee notes that, among the points falling within the competence of CESREEE, there is no explicit examination of the

ethical issues raised by the research project. She proposes that the draft decree be amended so that the committee can rule, if necessary, on this point, which is distinct from the public interest.

Regarding the publication of opinions by the health data platform:

The draft article 95 of the decree provides that for the processing operations authorized by the Commission, the reasons for the committee's opinion and the supporting elements are published by the health data platform, at the end of the research, the study or evaluation.

The commission proposes that all the opinions issued by CESREEE be published, whether the request has been the subject of an express decision of authorization or refusal by the commission or has been deemed accepted pursuant to the provisions of the Article 66 (V) of the Data Protection Act.

For the sake of transparency, and insofar as all processing for research, study or evaluation purposes must serve a purpose of public interest, the committee proposes that these opinions be published in the public directory at when the panel's decision is published or when the application is deemed to have been accepted, and not at the end of the search, study or assessment.

It also suggests that, at the very least, the meaning of the opinion(s) rendered should be published when the request is not forwarded to the commission. On the composition of CESREEE: Concerning the appointment of members and the composition of CESREEE:

Article 1 of the draft decree provides for the modification of article 93 of the decree of 29 May 2019 relating to the composition of CESREEE. This draft article modifies the procedures for appointing the members of the committee.

In general, the commission expresses the wish that the composition of CESREEEs reflects the diversity of the actors intended to use SNDS data.

It notes that the National Consultative Ethics Committee - whose mission is to give opinions on ethical problems and social questions raised by progress in knowledge in the fields of biology, medicine and health - will propose a single representative. Beyond this appointment, the committee emphasizes the importance of ensuring a balance of expected skills, including in terms of ethics, when appointing the other members of CESREEE.

Finally, the committee notes that the procedures for renewing the terms of office of committee members are no longer provided for in the draft. It proposes that these modalities be reintroduced there.

Concerning the solicitation of external experts:

The committee notes that draft article 93 of the decree supplements the provisions mentioned in the current article 95 of the decree of 29 May 2019 concerning the solicitation of outside experts.

The draft article 93 provides that the committee may call upon outside experts chosen by the chairman of the committee on the proposal of its members, in particular the representatives of the data producers concerned by the processing requests . The committee is wondering what is meant by representative of the data producers concerned, the terms of their solicitation and their role. In this respect, if necessary, it considers it useful to consult the representative of the committee in charge of the evaluation of research projects, studies or evaluation in the field of health, when the project aims to reuse data from a health data warehouse.

Concerning the internal regulations of CESREEE:

The draft article 95 of the decree specifies the content of the internal regulations of CESREEE which must now define, in addition to what was initially provided for, the conditions for organizing simplified procedures during which it issues an opinion without debate and the rules of deliberation.

The commission proposes that mention be made in the decree of what the rules of procedure also specify: - the role of the vice-president of the committee;

- the procedures for appointing external experts as well as their role;
- the methods of recourse to the representative of the data producers, his role, the methods and frequency of his participation, as well as the articulation of his participation with the decisions of the governance bodies of the data controllers, including when the reuse of data from a health data warehouse is envisaged, the internal committee in charge of the evaluation of research projects, studies or evaluation in the field of health;
- the procedures for publishing the opinions of the CEREES. Finally, the committee notes the absence of transitional provisions to ensure the continuity of the activity of the CEREES. It proposes, if the decree were not to be modified on this point, that the internal regulations of CESREEE determine the fate of application files submitted prior to the entry into force of the law on the organization and transformation of the health system. , and more particularly for those having been the subject of a reserved or unfavorable opinion of the CEREES and requiring a new opinion before transmission of the request to the commission.

On the organization of CESREES meetings:

The committee notes that the draft article 95 of the decree abolishes the periodicity of the meetings of the CESREES initially

provided for in the decree (the CEREES meets at least ten times a year when convened by its president).

It draws the Ministry's attention to the need to maintain a sufficient number of meetings in order to allow files to be examined at a frequency leading to fluid and regular transmission of files to the commission.

On the composition of the audit committee of the National Health Data System:

The draft article 101 of the decree aims to modify the composition of the SNDS audit committee, now composed of the president of the data platform or his representative, instead of the president of the National Institute for Health Data or his representative.

The commission notes that the health data platform is qualified as the processing manager of the national health data system, just like the National Health Insurance Fund.

On the public directory made available by the single secretariat:

Article 110 of the decree of 29 May 2019, which appears in sub-section 3 relating to simplified procedures, provides that processing which is not registered in the public directory mentioned in article L. 1121-15 of the Public Health Code are recorded in a public directory made available by the single secretariat.

The commission requests that the existence of this directory be mentioned in a specific article of the decree, in order to remove any ambiguity on the scope of the research to be entered in this directory, as well as the content of the information to be included therein.

It also proposes that all processing carried out in the context of research not involving the human person appear in a single public directory, that the processing be carried out within the framework of a commitment to comply with a reference methodology in accordance with article 73 of the Data Protection Act or an authorization request submitted to the commission.

Finally, it proposes that, by analogy with the legal provisions applicable to the SNDS, the authorization of the commission, the declaration of interests, the method as well as the results of the study or, where appropriate, of the studies when these are implemented within the framework of a single decision.

Insofar as the publication of the results by the data controller constitutes a decisive element in the assessment of the public interest of the research project, the commission suggests, as provided for by the (EU) regulation No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use, that provision is also made for the publication of a summary of the results written in a way understandable to lay persons. procedures for

informing the persons concerned: The draft article 111 of the decree relating to the information of the persons concerned by the reuse of their data contained in the SNDS now refers to the amending decree of decree no. 2016-1871 relating to the processing of personal data referred to as the national health data system.

Firstly, the commission draws the ministry's attention to the lack of clarity in draft article 111, which makes several references to the provisions of the public health code and the decree relating to the SNDS, which must itself be changed in the coming months. It therefore suggests that the ministry make these provisions more intelligible.

It also requests that it be specified that these information methods only apply in the event that the planned processing will be carried out exclusively using data from the SNDS.

Secondly, the committee draws the ministry's attention to the fact that the procedures for informing and exercising the rights of individuals, which will be provided for by the decree relating to the SNDS, must, on the one hand, relate to the constitution and operation of the SNDS as well as, on the other hand, on the reuse of this data, that the processing concerned contributes to a purpose mentioned in III of Article L. 1461-1 and responding to a reason of public interest or that they are necessary for the accomplishment of the missions of the services of the State, public establishments or organizations in charge of a competent public service mission.

On this point, the commission recalls that it will be particularly vigilant on the procedures for informing the persons concerned provided for by decree no. 2016-1871 relating to the processing of personal data known as the national health data system in the examination of the draft text.

The other provisions of the draft do not call for any particular comment on the part of the committee.

The president,

M. L. Denis