

Deliberation 2022-044 of April 14, 2022 National Commission for Computing and Liberties Nature of the deliberation: Opinion Legal status: In force Date of publication on Légifrance: Tuesday May 17, 2022 NOR: CNIL2214366X Deliberation No. 2022-044 of April 14, 2022 providing an opinion on draft decree relating to the data feeding the main database and the databases of the catalog of the national health data system (request for opinion no. 21014419) solidarity and health of a request for an opinion on the draft decree relating to the data feeding the main database and the databases of the catalog of the national health data system; 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 the directive 95/46/EC (General Data Protection Regulation or GDPR); Having regard to the Public Health Code (CSP), in particular its articles L. 1461-1 and R. 1461-2; After having heard the report of Mrs Valérie PEUGEOT, commissioner, and the observations of Mr Benjamin TOUZANNE, government commissioner, Being reminded of the following contextual elements The national health data system (SNDS), created by law n° 2016-41 of January 26, 2016, aims to provide personal data concerning health, in particular to implement processing for the purposes of research, studies or evaluations in the field of health responding to a reason of public interest. Initially limited to the "historical SNDS", the scope of the data categories currently composing it was widened by law n° 2019-774 of July 24, 2019. Thus, when they are processed for one of the purposes mentioned in Article L. 1461-1 III of the Public Health Code (CSP), the categories of data referred to in Article L. 1461-1 I of the CSP make up the SNDS ("extended" SNDS) and are subject to compliance with all the related provisions (compliance with the security baseline, terms of transparency, etc.). While this legal attachment to the "expanded SNDS" does not, on its own, lead to migration within a centralized database, some of this data is nevertheless intended to be gradually integrated into a "centralized SNDS" by the Caisse Nationale Health Insurance (CNAM) and the Health Data Platform (PDS). This "centralized SNDS" is made up of a main database (to date including the "historical SNDS") and a catalog including other databases considered relevant for research players. The latter can be of a varied nature and scale (databases held by a private body, cohorts, etc.). This integration will involve the migration of data to the CNAM and/or the PDS (only the latter will have the catalog). The implementation of the "centralized SNDS" is governed by decree no. 2021-848 of 29 June 2021 (hereinafter the "SNDS decree"). In order to complete its implementation, this decree provides in article R. 1461-2 of the CSP that an order, issued after consulting the Commission, lists the data falling under 1° to 11° of I of article L. 1461-1 of the CSP which feeds the main database, sets the methods of feeding this base and designates the databases appearing in the catalog.

Although article R. 1461-2 of the CSP does not reference only to the methods for supplying the main database, this decree also specifies the methods for supplying the catalog and the guarantees ensuring the legality of this processing. The Commission therefore considers that by referring to a ministerial decree the task of designating the databases feeding the catalogue, the Prime Minister implicitly but necessarily intended to entrust this decree with the task of specifying the conditions for feeding the catalog database. This is the purpose of the draft order, resulting from an amending referral, submitted for opinion to the Commission.

Issues the following opinion on the draft order

On the general structure of the text

If this draft order does not proceed the creation of personal data processing, the categories of data making up the SNDS being already provided for by the CSP, it makes it possible to list, on the recommendation of the Strategic Health Data Committee, the databases intended to enrich the main database and feed the "centralized SNDS" catalogue. With regard to the catalogue, this draft decree aims to set a minimum base of guarantees, both legal and technical, which must be detailed by the agreements concluded between, on the one hand, the managers of the databases intended to be in the catalog and, on the other hand, the PDS. It results from article 3 of the draft decree and from the exchanges with the ministry that, with regard to the catalog base: the designation of a base as having to appear in the catalog and the resulting legal regime result from the sole entry into force of this decree; the transmission of data is subject to the signing of an agreement between the initial processing manager of the database and the PDS, part of which content is provided for in Article 4 of the draft. Thus, the Commission considers that the data from the databases referred to in Article 3 of the draft should only feed the catalog if an agreement is concluded with the producer to this effect.

definition of cry Objective and precise third parties that may lead to the deposit of a database in the main database or the catalog or the changeover within the main database of a database appearing in the catalog is essential to guarantee the adhesion and the confidence of the actors of the ecosystem and the sustainability of this system. In this respect, the Commission asks that the work initiated by the Strategic Health Data Committee be continued as a matter of priority, before any new referral amending the order.

On the enrichment of the main database of the "centralized SNDS"

On the main database enrichment criteria

Article R. 1461-2 of the CSP provides that the main database includes data relating to the entire population. According to the Ministry's details, a processing operation may initially be entered in the catalog before being fed into the main database, provided that it meets the aforementioned condition. The Commission is renewing its request for clarification, already formulated in its deliberation no. 2020-106 of October 29, 2020 providing an opinion on the draft SNDS decree, of the basic concept "covering the entire population", insofar as it will be decisive for the inclusion of a treatment in the

main database and where this integration has consequences in terms of information, exercise of rights and security measures to be implemented. On the enrichment by data from the SI-DEP and "Vaccin-covid" databases draft article 1 provides that the "Vaccin-covid" and "SI-DEP" databases feed the main database of the "enlarged SNDS" and article 2 lists the categories of data from these databases that will be added to it. article provides that several types of data relating to health professionals from the "Vaccin-covid" database will feed the main database: on the one hand, the identification of the health professionals who respectively carried out the consultation prior to vaccination and each injection; on the other hand, the identification numbers of healthcare professionals and persons under their responsibility who carried out the prior consultation and vaccination. The Commission considers that, in accordance with the provisions of Article R. 1461-4 of the CSP, the main SNDS database does may include data that directly identifies healthcare professionals. It notes that the draft order will be amended to refer only to the "health professional identification number". More generally, the persons concerned must be informed of this in accordance with the provisions of the GDPR: concerning the "Covid-Vaccine" database, the Commission requests that the information media of all joint data controllers, in particular those of the CNAM, be put updated and that a reference to the dedicated web page of the DREES is made; the Commission notes that the site of the Ministry of Health providing information for the persons concerned by this processing will be updated and that a reference will be made to the dedicated web page of the DREES. As regards the procedures for exercising the right of opposition, it notes that: the provisions of article R. 1461-9 of the CSP provide that the right of opposition provided for in article 21 of the GDPR as well as in article 74 of the law "Informatique et Libertés" does not apply to the data of the main database within the framework of the constitution of the SNDS; the provisions of article 13 of decree no. 2020-551 of May 12, 2020 and of Article 5-III of Decree No. 2020-1690 of December 25, 2020 provides that data subjects whose data are processed in the "SI-DEP" and "Vaccin-covid" databases benefit from a relative right of opposition transmission of data for research purposes to the PDS and the CNAM. The Commission notes that the Ministry has undertaken to modify the information documents intended for the persons concerned in order to clarify the terms exercise of the right of opposition. On the conclusion of an agreement prior to the enrichment of the main database The ministry specified that the transmission in the main database of the relevant data (to date, the " and " Vaccin-covid ") will only take effect after the conclusion of an agreement between the managers of these databases and the CNAM. The project mentioning such a device only with regard to the supplying the catalog base, the Commission recommends that the p The draft decree also provides for the conclusion of an agreement when the database integrates the "main

database", in particular in the event that a database, initially registered in the catalog, would come to integrate the main database of the SNDS. supplying the catalog of "centralized" SNDS databases On the processing intended to supply the catalogueArticle 3 of the draft designates the databases which will supply the catalog and Article 4 provides that the initial managers of these bases keep them in their own information systems, under their responsibility. This same article also provides that the PDS is responsible for storing and making available a copy of these databases, which constitutes part of the "centralized SNDS". The Commission recalls that the initial managers of these databases must respect the compliance framework of the formality which was, where applicable, initially carried out with it. In fact, inclusion in the SNDS catalog has neither the purpose nor the effect of modifying the essential characteristics of this processing, particularly with regard to the retention period of the data. The Commission considers that only regularly constituted databases should be able to populate the catalog. To do this, it considers that it would be appropriate for it to be associated as far upstream as possible with the work of the Strategic Committee on the assessment of the advisability of listing databases in the catalogue, in which it could participate under the provisions of article 6 of the decree of June 29, 2021 creating it. Finally, it recalls that it will be particularly vigilant and will exercise its powers of control to ensure that the databases listed in the catalog are regularly constituted and implemented .On the categories of data that can be fed into the catalogueAccording to article 4 of the draft decree, the agreement concluded between the person in charge of the database and the PDS will specify the categories of data that will be fed into the catalogue.The Commission draws the attention of the Ministry on the provisions of the decree of November 29, 2019 approving an amendment to the agreement establishing the PDS which provides that it is authorized to process donations contextual "when relevant to user demand". The Commission understands that when a database contains data relating in part to the SNDS and contextual data which would be indivisible, the entire database could be transmitted to the PDS. It recalls that only the categories of data referred to in Article L. 1461-1 I of the CSP and strictly necessary for the purposes of the SNDS can feed the databases of the "centralized SNDS". On the information by the person in charge of the database Article 4 of the draft provides that the persons in charge of the databases carry out individual information of the persons concerned, by paper or electronic means, relating to the supply of the catalog of the SNDS, except if the provision of such information proves impossible or would require disproportionate efforts within the meaning of Article 14 of the GDPR. The terms under which this obligation must be complied with must be set out in the agreement concluded between the database manager and the PDS. This information, which is mandatory for all data controllers, must comply with the provisions of Articles

13 or 14 of the GDPR. The Commission recalls in this respect that: as a matter of principle, data subjects must be individually informed when processing their personal data, whether it is a direct collection or indirect data collection; only in the case of indirect data collection, in accordance with the provisions of Article 14-5-b of the GDPR, the obligation to provide individual information to the persons concerned may be subject to exceptions, in particular in the event that the provision of such information would prove impossible, would require disproportionate effort or would seriously compromise the achievement of the objectives of the processing nt. In such cases, the controller shall take appropriate measures to protect the rights and freedoms, as well as the legitimate interests of the data subject, including by making the information publicly available; when the data collection, even indirect, is carried out prospectively, individual information must, as far as possible, be issued to the persons concerned; the information documents must mention that the data will be added to the catalog or be supplemented for this purpose. Finally, the Commission requests that the reasons justifying to make an exception, for all or some of the persons concerned, to the provision of individual information, as well as the appropriate measures implemented to make the information publicly available, are explicitly described in the agreement. It would also like further discussions to take place with the Ministry and the PDS on this point. On the procedures for exercising rights The agreement provided for in Article 4 of the draft, concluded between the controller and the PDS, will specify the procedures conservation of correspondence tables ("secret conservation"). These details are essential to allow individuals to exercise their rights. The Commission considers that the agreements should at least indicate, under these terms and conditions: the organization responsible for this storage; the storage conditions in the event that the person responsible processing wishes to end the processing and/or delete the processed data; the storage methods depending on whether the data is matched using the registration number in the national identification directory of natural persons (NIR) of persons or not. , the Commission considers that a minimum period of one month between the signing of the agreement and the actual entry of the data into the catalog contributes to guaranteeing the effectiveness of the right of opposition available to individuals pursuant to II of Article R. 1461-9 of the CSP. This period must be determined according to the characteristics of the processing and in particular according to the number of people concerned, the methods of information and the age of the data processed. On the agreements organizing the entry of data into the catalog Article 4 of the draft sets out the main principles which must be detailed in all agreements entered into with data producers, in particular with regard to: the methods of information and the exercise of rights at the level of the data producer and the PDS; the distribution of roles and responsibilities; the security measures governing the transmission of data and their

pseudonymization. The terms agreed in the agreement must make it possible to ensure effective compliance with the obligations arising from the GDPR. On the application of the SNDSL security reference system applicable to the operations of supplying the catalog must comply with the applicable security reference system. able to the SNDS provided for by the order of 22 March 2017. The Commission recalls that this reference system will have to be updated to draw the consequences of the changes introduced by the "SNDS decree", in particular with regard to the role of the PDS in the implementation of the SNDS and the deployment of the catalogue. It considers that this update should therefore take place prior to the conclusion of the agreements with the data controllers and the addition of the catalog. The Commission considers, with regard to the provisions of the reference system currently in force, that the "SI-DEP" processing and "Vaccin-covid" must be qualified as "source systems" of the SNDS. Finally, it questions the qualification as "source systems" of the processing operations whose inclusion in the SNDS catalog is envisaged by this draft text .The other provisions of the draft order do not call for comments from the Commission.The PresidentMarie-Laure DENIS