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SUBJECT: draft decree of the President of the Republic concerning Provisions Regulation implementing Law 30 June 2009, n. 85 on the creation of the national database of DNA and the central laboratory for the national database of DNA, according to Article 16 of Law no. 85 of 2009.

(PRELIMINARY EXAMINATION)

(PRESIDENCY - JUSTICE - INTERNAL - HEALTH - WORK AND SOCIAL POLICY ')

For the purposes of art. 2, paragraph 3 of Law 23 August 1988, n. 400, and art. 3, paragraph 4, of D.P.C.M. November 10, 1993, transmitting the pattern of the measure in question, to be submitted to the Council of Ministers, after examining the Preconsiglio.

An Order from the
PRESIDENT OF THE COUNCIL OF MINISTERS

SCHEME OF REGULATION LAYING DOWN PROVISIONS FOR THE IMPLEMENTATION OF THE LAW June 30, 2009, # 85, ON THE ESTABLISHMENT OF NATIONAL DNA DATABASE AND CENTRAL LABORATORY FOR THE NATIONAL DNA DATA BANK, IN ACCORDANCE WITH ARTICLE 16 OF LAW NO 85 OF 2009.

THE PRESIDENT OF THE REPUBLIC

HAVING REGARD to Articles 87 and 117 of the Constitution;

HAVING REGARD to Article 17, paragraph 2, of the law 23 August 1988, n. 400;
CONSIDERING law June 30, 2009, n. 85;

CONSIDERING in particular, l'articolo 16 of the said Law. 85 of 2009, under which they are governed, with one or more regulations, the organization, it functioning, the mode of access to the national database of DNA and the central laboratory for the national database of DNA as well as the criteria and the modalities and procedural techniques for collecting and la conservation of biological samples;

VISA altresì, l'articolo 13, paragraph 4, of Law no. 85 of 2009, by which, with the aforementioned regulations, are defined in consultation with the Authority for the protection of personal data, the storage time of biological samples and DNA profiles entered into the national database of DNA;

CONSIDERING the decision of the EU Council of 23 June 2008, n. 2008/615 / gal on strengthening cross-border cooperation, particularly in combating terrorism and cross-border criminality;

VIEW Ia decision of the EU Council of 23 June 2008, n. 2008/616 / JHA on the implementation of Decision 2008/615 / JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border criminality;

VIEW Ia decision of the EU Council of 30 November 2009, n. 2009/905 / gal on Accreditation of forensic service providers carrying out the activities of laboratorio according to EN ISO / IEC 17025;

GIVEN the resolution of the Council of the European Union of 30 November 2009, n. 2009 / C 296/01 on the exchange of results of DNA analysis;

It DEEMED appropriate to regulate by a single regulation the above aspects of the national database of DNA and it laboratorio central Ia national database of DNA;

ACQUIRED dated July 31, 2014 ii opinion of the Ia for protection of personal data, in agreement with which they were defined storage times of biological samples and DNA profiles entered into the national database of DNA;

ACQUIRED on 5 August 2014, the opinion of the National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV);

CONSIDERING the preliminary resolution of the Council of Ministers, adopted at the meeting of ...;

HEARING en Opinion of the State Council, expressed by the Advisory for regulations at the meeting of,

ACQUIRED il opinion issued by the competent parliamentary committees of the Chamber of Deputies and the Senate;

VIEW Ia resolution of the Council of Ministers, adopted at its meeting,
ON THE PROPOSAL of the Minister of Justice, Minister of the Interior, the Minister of Health and the Minister of Labour and Social Policy, in consultation with the Minister of Defence, it Minister of Economy and Finance and it Minister of Agriculture and forestall;

IT IS ISSUED
the following regulations:

CHAPTER I
General provisions

ART. 1
(Subject)

1. This Regulation regulates the modality of operation and organization of the national database of DNA and the central laboratory for the national database of DNA, referred to in Article 5 of Law 30 June 2009, n. 85.
2. This Regulation also regulates the exchange of DNA data for the purposes of cross-border cooperation under Decision No. 2008/615 / JHA and n. 2008/616 / JHA of 23 June 2008, relating to it strengthening cross-border cooperation, particularly in combating terrorism and cross-border criminality as well as for the purposes of international police cooperation under Article 12 of Law 85 of 2009.
3. The processing of personal data in application of this Regulation and carried out in compliance with the regulations regarding the protection of personal data, in conformity with the Code regarding the protection of personal data contained in the Decree of 30 June 2003, n. 196, as amended.

ART. 2
(Definitions)

1. For the purposes of this Regulation shall apply:
 - a) reads: Law 30 June 2009, n. 85;
 - b) Database: national database of DNA;
 - c) Central Laboratory: Central Laboratory for the national database of DNA;
 - d) AFIS (Automated Fingerprint Identification System): automated system for identifying fingerprints of Casellario central identity of the Ministry of the Interior, Department of Public Safety, located at the Central Anti-Crime of the State Police, Scientific Police Service ;
 - e) (CUI Unique Code ID): alphanumeric code generated automatically by the AFIS system and uniquely linked to the person;

f) LIMS (Laboratory Information Management System): an information system suitable to manage data and workflow of a laboratory;

g) biological sample: quantity of biological substance taken on the subject of the typing of the DNA profile;

h) exhibit biological traces found on a specimen obtained at the scene of a crime still on 0 relating to the offense;

i) country code: alphanumeric code that uniquely identifies its country, according to a coding technique established by the head of the Bank data in conformity with the decisions n. 2008/615 / JHA and n. 2008/616 / JHA, and subsequent amendments, and for the purposes of international police cooperation under Article 12 of the law;

l) code organization: alphanumeric code that uniquely identifies the Police Force or the establishment of highly specialized, according to a coding technique established by the head of the Database;

m) laboratory code: alphanumeric code that uniquely identifies the laboratory carrying out the typing of DNA profiles, according to a coding technique established by the manager of the database,

n) code profile DNA code that identifies the source of the biological sample and the biological specimen from which it is typed DNA profile, according to a coding technique established by the head of the Bank data, in conformity with the decisions n. 2008/615 / JHA and n. 2008/616 / JHA as amended as well as to the finality of international police cooperation under Article 12 of the law;

o) code removal: alphanumeric code that uniquely identifies its biological sample obtained by the person referred to in Article 9 of the law or by the relatives of the missing person undergoing withdrawal and does not allow direct identification of the subject. It is automatically generated by the system according to AFIS encoding technique established by the head of the Database;

p) finding biological code: alphanumeric code that uniquely identifies its biological specimen and does not allow direct identification of the biological specimen or a dead body or corpse remains. It is generated automatically by a LIMS, which also contains the following information, according to a coding technique established by the head of the Database:

- 1) Code of the institution;
- 2) code laboratory;

q) reference number: alphanumeric code that uniquely identifies its biological sample and the biological finding it, in conformity with the decisions n. 2008/615 / JHA and n. 2008/616 / JHA, and subsequent amendments, and **for finality of international police cooperation under Article 12 of Law**, consists of the following elements:

- 1) country code;
- 2) code of the DNA profile;
- 3) code or code finding biological sampling;

r) treatment: any operation or set of operations carried out without help of electronic means, in concerning the collection, recording, organization, storage, in consulting, development, modification, selection, typing, in comparison, use, interconnection, block transfer, in communication, diffusion in, in erasure and destruction of data;

s) Access: consultation including computer science, data and information contained in the database;

t) identification data: personal data that allow direct identification;

u) DNA: deoxyribonucleic acid, the repository of genetic information, in the form of a linear sequence of nucleotides, the bearer of hereditary information;

v) DNA profile: alphanumeric sequence derived from the DNA and characterizing each individual;

z) national contact point or abroad: authorities, national or esters, designated for data exchange and for the finality of international police cooperation.

2. For the purposes of this Regulation also aims to:

a) Typing: all the transactions laboratory techniques that lead to the production of the DNA profile;

b) locus: the physical location on a chromosome of a gene or of a marker in a DNA region;

c) allele: DNA variants present in the same locus;

d) marker: DNA sequence known and identified with specific tests;

e) Nomenclature of a genetic marker: designation of a marker located in the physical region of the gene corresponding to that of the gene itself; if the genetic marker is outside the region of the gene, the name identifies the location on chromosome;

- f) electropherogram: the result of the electrophoresis of the sequence of DNA fragments used to extrapolate the DNA profile;
- g) allele drop-out: Failure DNA amplification of one allele, which leads to an incorrect determination of a heterozygous condition;
- h) stutter: artefattuale band with a different number of repetitions to wild parent;
- i) PCR (Polymerase Chain Reaction): enzyme polymerase chain reaction; I) primers: synthetic fragments of DNA used for PCR Ia;
- m) thermocycler (thermal cycler): laboratory instrument used to perform the cycles of DNA amplification;
- n) allelic ladder: the set of alleles at a locus most representative in the world;
- o) set-up: the preparation phase during one of the techniques of DNA typing;
- p) STR (Short Tandem Repeat): regions of DNA comprise DNA sequences repeated in tandem if present on autosomal loci, or non-sexual, are generally referred to as STR, if present on sex chromosomes are referred to as Y-STR or X -STR;
- q) mtDNA: abbreviation for mitochondrial DNA.

CHAPTER II

Organization and operation of the database and the Central Laboratory, mode of acquisition biological samples, management and typing of DNA profiles, treatment and access to data

SECTION I

Organization and operation of the database and the Central Laboratory

ART. 3

(Organization and operation of the database and security measures)

1. The Database 6 located at the Ministry of the Interior, Department of Public Security, Service for the information system of the Central Directorate of the Joint Criminal Police.
2. Database 6 organized according to criteria of physical and logical separation from other systems processing data managed by the Centre under Article 8 of the Law of 1 April 1981, n. 121, in order to ensure Ia full autonomy compared to the latter.
3. Database 6 designed for the collection and comparison of DNA profiles, second () as required by law. For the management of DNA profiles of the software database 6 arranged on two levels.

4. The first level 6 used for investigative purposes at national level. The second level 6 also used for the finality of international police cooperation in conformity with the decisions n. 2008/615 / JHA and n. 2008/616 / JHA, as amended as well as to the finality of international police cooperation under Article 12 of the law, according to the procedures laid down in Article 10 and Chapter III.

5. The continuity of operation of the database 6 secured by a specific secondary system remotely activated in the event of a disaster or other event of exceptional gravity declared by the responsible person referred to in Article 26 and adopted in conformity with article 50-bis of Legislative Decree 7 March 2005, n. 82.

6. they secondary system referred to in paragraph 5 shall be adopted in the same security measures, including physical and logical, on the processing of data provided by the database.

7. Access to the database and processing operations data are available only to authorized operators and designated in charge of the processing of personal data in accordance with Article 28 of Legislative Decree 30 June 2003 n. 196, as amended, according to predefined authorization profiles, possess authentication credentials after passing a computerized procedure for strong authentication.

8. For the exclusive finality verification of lawfulness of the processing, access and the operations referred to in paragraph 7 are recorded in special log file cannot be modified that are kept for twenty years.

9. Decree of the Minister of the Interior in consultation with the Minister of Justice it, heard it Authority for the protection of personal data, to be taken within thirty days from the date of entry into force of this Regulation, they are defined profiles for authorization, authentication procedures, registration and log analysis.

ART. 4

(Organization and operation of the Central Laboratory and security measures)

1. Laboratory II central ii placed at the Ministry of Justice, Department of Penitentiary Administration - Directorate General of prisoners and treatment.

2. The Central Laboratory has facilities in robot capable of performing the following steps of DNA typing:

- a) the collection, cataloging and conservation of the biological sample;
- b) set-up of the sample;
- c) possible phase extraction of DNA;
- d) possible quantification stage;
- e) amplification of DNA by PCR;

f) reading and interpretation of the DNA profile through automatic sequencer.

3. it the Central Laboratory for the overall management of the flow of work and laboratory data uses a LIMS that ensures the traceability of the biological sample, the various stages of DNA typing and transactions carried out by staff, including the directors system, and the recording can not be modified by any changes made to the data.

4. The continuity of the operation of a central LIMS Laboratory secured by a specific set of technological measures for back-up of the LIMS which it access restricted to only authorized operators through a procedure of authentication and authorization.

5. Access to the LIMS the Central Laboratory are available only to authorized operators, according to predefined authorization profiles, following successful completion of an authentication process. Access and the operations performed on the system LIMS are recorded in special log file can not be modified. Access recordings are kept for twenty years. Records of transactions are kept for ten years. The authorization profiles, authentication procedures, registration and log analysis, are specified in the decree referred to in Article 3, paragraph 9.

6. Access to the premises and cabinets for the storage of biological samples and electropherograms are available only to authorized operators and possess special access keys and are registered, according to the rules set by the decree referred to in Article 3, paragraph 9.

SECTION II

Modality of sample acquisition and biologics management and typing of DNA profiles

ART. 5

(Acquisition of the biological sample of the persons referred to in Article 9 of the law)

1. The persons referred to in Article 9 of the Act shall be subject to the levy of two samples of oral mucosa, alio purpose of allowing the driven pulley repeat DNA typing, following identification of the same via electronic access all'AFIS and recording of transactions identification and removal, by the organ proceeding in AFIS. II withdrawal 6 made only if the subject was already 6 previously subjected to a similar operation, except in cases where it was already arranged Ia destruction of the sample in accordance with Article 24 and again fulfills the conditions laid down in Article 9 of Law, without prejudice to the recording in the AFIS system in order to update the data.

2. Except as provided in paragraph 3, draw provides, both for those minors and adults, the staff of the prison service, specifically trained and trained.

3. In the following cases, draw provides the personnel of the police force delegated the execution of the restrictive measure, specifically trained and trained:

- a) application of an order that has the house arrest, la stay at home or placement in the community;
- b) 'arrest or detention, with esciusione cases in which, after the judgment of validation, is willing l'associazione to a prison;
- c) application of a measure alternative to detention, if the subject 6 in custody;
- d) application of a security measure of imprisonment, also in the form of placement in the community.

4. Biological samples referred to in paragraph 1 are taken according to the following ways:

- a) staff conducting procurement wears protective equipment whenever proceeds to a withdrawal;
- b) the withdrawal is made by an oral swab to dry that is rubbed on the inside of the cheek or on the gums for an appropriate time;
- c) any biological sample 6 placed in a separate container;
- d) the biological sample 6 stored at room temperature.

5. Both biological samples are sent to the Central Laboratory in pH. ' soon as possible in a single package the sealed burglary, using organizational mode, which streamline la transmission by persons referred to in Article 9, paragraph 6, of the law, even using specialized couriers that ensure the integrity of the envelope itself la and its traceability. On each of the samples 6 purpose identical label must contain, in readable format:

- a) the office alarm code;
- b) the identification code of the operator who took the sample of biological samples;
- c) the reference number;
- d) the date of sampling.

6. The Central Laboratory provides the following tasks:

- a) computer record of the package containing the two biological samples with modes that allow la traceability of transactions carried out by a specialist and the recording of all changes made to the data;
- b) opening of the sealed package containing the two biological samples, placing a sample in a new envelope of security, which is preserved for future investigations or inspections, and subjecting l'altro to DNA typing;
- c) affixing in an envelope of the part of the biological sample unused, with application to closing a new label; closing the aforesaid casing in a security envelope suitable for the conservation;

d) insertion electronically the DNA profile in the database, the relevant reference number, the organization code and code of laboratory;

e) if it is determined that the DNA typing of the first of the two biological samples gave negative results or partial, it's Central Laboratory staff shall inform the AFIS. Once you find the person to whom it refers it biological sample, AFIS notify the office signaling to proceed, subject to authorization Judicial Authority, the repetition of the levy. In case of repetition of the levy, warning the AFIS communicates that it informs central laboratory why are responsible for the destruction of both biological samples and DNA profiling part. In case of impossibility of repetition of the levy, the office signaling by the Authority shall collect judicial too! 'Authorization to process it according to sample, duly informing the AFIS for subsequent communication to the central laboratory.

7. The flow of the biological sample, from the time of collection until the arrival at the Central Laboratory to run through a computerized procedure, accessible from the portal database, reserved for only operators authorized through a procedure of authentication and authorization.

ART. 6

(Levy, management and typing DNA profiling of biological specimen acquired in torso criminal proceedings, in the event of termination of persons scornparse and in the case of discovery of corpses and cadaverous remains unidentified)

1. In cases of complaint of a missing person, the judicial police acquires, where deemed necessary, the information elements of the missing persons and objects to the exclusive use of the same, in order to obtain it DNA profile. To increase it power identification DNA profile, put, be required to submit voluntarily to the relatives of the biological sampling. In this case it subject 6 undergoes an identification procedure by acquisition of its personal data and details of the identification document.

2. The personal data subjects relatives of paragraph 1 shall be stored in a subset AFIS and DNA profiles stored in a subset of the database consulted only for the identification of the missing person.

3. A person who logs in the subset of AFIS, before taking it, checks for a previous withdrawal. In case of failure makes ii two sampling mucosal bream and the withdrawal transaction is recorded organ proceeding in the subset of AFIS according to modality referred to in Article 5.

4. For the overall management of the data flow laboratory, the laboratories of the police forces or the laboratories of the institutes of high specialization they use a LIMS system according to the modality provided for in Article 4, paragraph 5, which guarantees the traceability of biological specimen, the various stages of DNA typing

and transactions carried out by staff at the lab, including system administrators, and the recording can not be modified by any changes made to the data.

5. If staff on duty at the laboratories must not process the biological specimen using a LIMS that automatically generates code finding it organic. If above code, used in the laboratory during the various stages of typing DNA profiling, does not allow direct identification of the biological specimen.

6. The staff on duty at the laboratories of the Police Forces, after making the typing of the biological specimen, available on Judicial Authority providing power to electronically in the database of the DNA profile, the relevant reference number, code body and the laboratory code.

7. The inclusion electronically DNA profiles and data referred to in paragraph 6 obtained from biological samples in the course of criminal proceedings which typing 6 was not made by the laboratories of the police forces is done by laboratory personnel of the Force Judicial Police indicated by the Authority. The transmission of the DNA profile of the institute of highly specialized, via computer, to its laboratory identified by the Authority Judicial Police Force, takes place according to the rules set by the decree referred to in Article 3, paragraph 9.

8. The electropherogram used by accredited laboratories other than those of the police to extract its DNA profile is stored, for verification purposes and quality of the data, the records of the same laboratory that carried out the typing of the DNA profile in shape not available with modes of automated searches and sent to the database in electronic form for the purposes of Article 13, paragraph 4, through an application of the same portal reserved only operators specifically authorized by a procedure of authentication and authorization.

9. The provisions of this Article, as far as compatible, also apply in the event of discovery of corpses and cadaverous remains unidentified.

SECTION III

Modality of treatment and access by computer and telematic data collected in the database and Central Laboratory

ART. 7

(Supply of the Bank's Data)

1. The Bank data supplied by the operators of the judicial police in charge of the processing of personal data specifically authorized, in service at the laboratories of the Police Forces and the Central Laboratory it by inserting electronically DNA profiling and its reference number of the Code and the entity code laboratory. Without prejudice to the provisions of Articles 25, paragraph 4, 29, paragraph 4, 30, paragraph 1, letter a), and 31, paragraph 2, the further processing of the data allowed the aforesaid staff exclusively for finality of matching with Ia numerical

sequence electropherogram provided by the Laboratory. The aforementioned personnel and personnel employed by the Bank data denied access to the AFIS system.

2. Decoding the code levy performed by qualified personnel using the AFIS system, specifically enabled for this transaction, with modes that allow the tracking of transactions. At staff enabled the use of the AFIS system and that access to the LIMS laboratory as well as the database.

3. Decoding the code finding biological 6 performed by trained personnel, on duty at the laboratories of the Police Forces, which has included it in DNA profile database. The predicted 6 staff denied access to the AFIS system. In the case of corpses, cadaverous remains, relatives of the missing person the activities of decoding may be performed only for the identification of the missing person.

ART. 8
(Central Laboratory)

1. The treatment of the data collected in the Central Laboratory to allow operators to judicial police on duty at the Central Laboratory itself it specifically authorized and designated in charge of the processing of personal data in accordance with Article 28 of Legislative Decree 30 June 2003 n. 196, as amended, exclusively for finality of application of this Regulation, with the approval of the Authority court under Article 12, paragraph 2, of the law. The predicted 6 staff denied access to the AFIS system.

SECTION IV
Modality of consulting the information requested in the national

ART. 9
(Consultation of the requested data, the comparison of DNA profiles and content of requests and responses to Database)

1. II staff on duty at the laboratories of the Police Forces and the database has the faculty to carry out a consultation with la search it and comparison of DNA profiles.

2. The consultation may be carried out at the national level, only in individual cases, and the outcome of the comparison notified to automated laboratories of the police forces who have entered it DNA profile, using it in the portal database.

3. In case of a match between a DNA profile submitted and DNA profiles recorded in the database, the provisions of Article 10, paragraphs 6, 7, 8 and 9.

4. A request for consultation and automated responses made it through the portal of the database must contain the police the following information required by the portal's database:

- a) its normative reference for the motivation of the crime;
- b) office of identification applicant and the operator;
- c) the name of the office and the judicial identification of the Authority, its number of criminal proceedings and the reference year.

ART. 10

(Inclusion criteria and comparison of DNA profiles and matching rules)

1. The DNA profiles are sent to the database in accordance with Articles 9 and 10 of the law through the portal database for gathering and comparisons.
2. Central Laboratory, the laboratory of the Police Forces and the institution laboratories highly specialized that feed the database are to be sent to the same database appropriate documentation, also by electronic means, about the test methods accredited and Rates of validity of the certificate. The Database provides the aforementioned documents, upon request, to the National Committee for Biosafety, Biotechnology and Life Sciences in Article 28 for the activities within its competence.
3. If, in a criminal case, we proceed to DNA typing profiles of more of the same subject, it is transmitted to the database only the DNA profile that shares the same loci.
4. The authorized under Article 12, paragraph 2, of the Act inserts the DNA profiles in the database only if obtained by methods accredited under ISO / IEC 17025, as amended. DNA profiles are inserted at the first level from a number of loci equal to seven. Only the DNA profiles that have a number of loci equal to or exceeding ten are inserted at the second level.
5. E 'prohibited the transmission to the second level of the database of DNA profiles consist of a mixture of more profiles. In the event of commingling of more DNA profiles where 6 distinguishable, quantitatively as the height of the peaks of the alleles, a major component of a minority component, transmitted to the second level of the database a single major component. II DNA profile of the latter component shall be traceable to an individual, a quantitatively major component must be at least 3 times a minority component results and it must be confirmed by a double experiment with two commercial kits that need to overlap a not less than 10 loci.

CHAPTER III

Provisions for automated search of the database for purposes of cooperation Border

SECTION I

Exchange of information for purposes of cross-border cooperation

ART. 11

(National Contact Point)

1. II national contact point for the exchange of data for the purposes of international police cooperation 6 identified in the Service for International Police Cooperation of the Central Directorate of Criminal Police of the Department of Public Safety.

2. For the purposes of article 13, paragraph 4, the national contact point with the collaboration of the database.

ART. 12

(Consultation, transmission and comparison of DNA profiles from abroad ('Italy))

1. The reference DNA profiles contained in the database, for the purposes of cross-border cooperation referred to in Article 1, paragraph 2, is allowed to contact points abroad, have the credentials of authentication and authorization for the comparison with DNA profiles contained on the second level of the database in accordance with the decisions n. 2008/615 / JHA and n. 2008/616 / JHA, as amended, in automated mode as well as for purposes of international police cooperation under dell'articolol2 the law according to the protocols and communication channels encoded internationally.

2. The transmission of DNA profiles between the national contact points puts) be carried out in automatic mode or second communication channels encoded at international level, ensuring the adoption of appropriate measures, including encryption, to ensure confidentiality and la 'integrity of the data transmitted.

3. The outcome of the comparison 6 notice, by it its reference number, organization code and code lab, because automated through an application portal of the database, the point of contact abroad.

4. Automated notification referred to in paragraph 3 and provided only if it comparison has resulted in a match of a number of loci or older according to Article 7 and Chapter I of Decision No. 2008/616 / JHA and the Resolution of the Council of the European Union n. 2009 / C 296/01 on the exchange of results of DNA analysis.

5. In case of success, la Database forwards with electronic automated mode similar communication to the national contact point and the lab has added ii DNA profile in the database, and performs activities for la preparation to receive subsequent requests Further information from the corresponding point of contact abroad as well as the activities referred to in Article 13, paragraph 4.

ART. 13

(Consultation, transmission and comparison of DNA profiles dalntalia to l'estero)

1. The judicial police who must seek a DNA profile in the international arena, see the foreign DNA databases through application of the portal database, via the national contact point in each case, according to a coding technique established by the head

Bank data in conformity with Articles 7, 8, 9, 10 and 11 of Decision No. 2008/616 / JHA as well as according to the protocols and channels of international comunicazione amended.

2. The outcome of the comparison 6 notice, by its reference number, organization code and code lab, because automated through an application portal of the database, the National Contact Point and the police requesting court as well as to laboratory you have entered the DNA profile in the database.

3. Automated notification referred to in paragraph 2 6 provided only if the comparison has resulted in a match of a number of loci or older according to Article 7 and Chapter I of Decision No. 2008/616 / JHA, or resolution of the Council of the European Union n. 2009 / C 296/01 on the exchange of results of DNA analysis.

4. In case of success, Ia Database shall verify the correctness of the DNA profile comparing the data entered in the database with the numerical sequence electropherogram provided by the laboratory, communicating the results to the national contact point, to allow it to evaluate the types and the number of subsequent requests for further available personal data and other information associated with the DNA profile corresponding to the hit, as indicated in Article 5 of Decision No. 2008/615 / JHA.

SECTION II

Provisions on the protection of personal data

ART. 14

(Scope)

1. The provisions of this section shall apply to personal data transmitted or received for finality of cross-border cooperation under the provisions set out in Section I.

ART. 15

(Finality of the treatment)

1. The personal data transmitted or received are processed for the finality specified in Article 1, paragraph 2.

2. The processing of data received from the national contact point in response to a request for search or comparison, 6 authorized solely for the purpose of:

- a) ensure Ia correlation between the compared DNA profiles;
- b) prepare and submit a request for mutual assistance in case of any difference;
- c) make the records referred to in Article 17.

3. The treatment of the data received 6 altresl admitted for purposes consistent with that 'for which they were provided and prior authorization of the Member State which transmitted, in accordance with national law.

4. The national contact point is the data that is transmitted from the contact point of another Member State for the finality specified in Article 1, paragraph 2, such treatment only if 6 necessary to make a comparison, respond by automated consultations or make the records referred to in Article 17. At the end of the comparison or automated response to consultations, data transmitted are deleted immediately unless it is necessary to further treatment for the purposes of paragraph 2, letters b) and c).

ART. 16

(Verifying how much of the data transmitted or received)

1. If national contact point of another Member State 6 informed of the existence of any instance in Article 33, paragraph 1, second period.

2. If it emerges that inaccurate data have been provided or should not have been forwarded, it national contact point of the other Member State shall be informed as soon as possible 6. Moreover, personal data supplied shall be corrected if they are inaccurate.

3. If you have reason to believe that the data received in response to a request for consultation are incorrect or should be erased, it national contact point will be communicated immediately to the national contact point of the Member State that sent them.

4. The personal data that should not have been received shall be deleted, data lawfully received shall be deleted:

a) if they are not or are no longer necessary for the purposes for which they were transmitted from the other Member State. If personal data have been received without request, it national contact point occurs immediately if they are necessary for the purposes for which they were provided;

b) at the end of the shelf life of the data under the national law of the Member State that has transmitted li where the authorities have indicated that the transmission period of up to national contact point at the time of transmission.

5. Proceed to the blocking of data where there is reason to believe that the cancellation of the same would undermine a legitimate interest of the person concerned, in accordance with national law. Blocked data may be, however, supplied or used solely for the purposes that have prevented la cancellation.

ART. 17

(Log of operations)

1. As part of the most extensive security measures taken in conformity with Articles 31 to 36 and Annex B of the Legislative Decree 30 June 2003 n. 196, as amended, all operations undertaken pursuant to this Chapter are recorded in special log files for the purpose of verification of the lawfulness of data processing.
2. Automated searching can be accomplished only by the national contact point duly authorized. Upon request, a list of six staff made available to the Authority for the protection of personal data, and the authorities responsible for data protection of other Member States.
3. The records referred to in paragraph 1, which also include information on the existence or absence of a positive response, include the following information:
 - a) the data supplied;
 - b) the precise date and the correct time of the transmission;
 - c) the name or reference code of the authority that it carries la and consultation of the authority that manages the database.
4. They are also registered ii reason for search or supply, and references of the staff who carried out the search and of what he requested.
5. Within four weeks of receipt of any request, sl national contact point providing records to the authorities responsible for data protection in the Member State concerned. Logs can only be used for purposes of monitoring data protection, there compreso it to security.
6. Logs are protected with suitable measures against misuse or inconsistent with the purposes for which they are registered. Logs are kept for two years and erased at maturity.

ART. 18

(Supervision and Control)

1. The control on the transmission and reception of personal data referred to in this Chapter to exercise the guarantee for the protection of personal data ', as provided by the decree of 30 June 2003, n. 196, as amended, including a report. The results of activity of control are preserved for eighteen months and deleted at maturity.
2. The authorities responsible for the records referred to in Article 17 carry out checks to verify the legitimacy of transactions Ia.

CHAPTER IV

Technical, method of analysis and storage of biological samples and storage times of samples biological and DNA profiles

SECTION I
Techniques and methods of analysis of biological samples

ART. 19
(DNA extraction)

1. For any phase extraction of DNA from biological samples are used commercial kits commonly used in the field of forensic science community and validated by the scientific literature in terms of yield quantity and quality of the extracted DNA.

ART. 20
(Sample preparation with robotic systems)

1. The preparation of the sample for the quantification stage, amplification and loaded on automated sequencer must be automated, in order to minimize the error human and have a high reproducibility of the data. The automated system must have appropriate documentation IQ / OQ or equivalent or higher showing the proper installation and proper functionality of the instrument according to the requirements.

ART. 21
(Quantification of DNA)

1. For any phase quantification of DNA are used commercial kits that allow you to check the amount of DNA present in the extract and the presence of PCR inhibitors.

ART. 22
(DNA amplification)

1. The instrument used in a thermal cycler with certification on reliability of temperature cycles used by the kit of DNA amplification.
2. The names of the markers used are those shown in the recommendations of the European Network of Forensic Science Institutes (ENFSI), used by Interpol and reflected in the Resolution of the Council of the European Union n. 2009 / C 296/01, as amended.
3. The types of markers that can be used in typing the DNA profile to be included in the database are STR, Y-STR, X-STR and mtDNA according to a coding technique established by the manager of the database in conformity with the decisions n. 2008/615 / JHA and n. 2008/616 / JHA as amended as well as to the finality of international police cooperation under Article 12 of the law.
4. The markers used to define the genetic profile useful for use in identifying staff (autosomal loci) must meet the following minimum criteria:

- a) be variations in the length or sequence, transmitted with Mendelian modality;
- b) be independent;
- c) have a high information value, that have a value of heterozygosity greater than 70 percent;
- d) have a sufficiently high number of alleles in the population.

5. The amplification of every single biological sample must be performed through the use of two commercial kits which have for it the same locus a different sequence of the primers, in order to avoid an incorrect assignment of alleles.

6. loci amplified by the two commercial kits need to overlap for at least ten loci.

7. The DNA amplification must always be equipped with it in the kit positive control and a negative control.

ART. 23

(Reading and interpretation of the DNA profile)

1. The determination of the genetic profile must be done using an automatic sequencer of nucleic acids for the electrophoresis of the DNA fragments and equipped with software dedicated to the subsequent reading and interpretation of the DNA profile.

2. For a correct assignment of alleles must be followed the following minimum criteria standards:

- a) each electrophoresis must have at least one ladder lico;
- b) in each electrophoretic run in each PCR sample it must be associated with an internal standard of known molecular weight;
- c) the assignment of the alleles of a DNA profile may be made only if all the peaks of the standard referred to in point b) have been properly assigned;
- d) the assignment of alleles of each DNA profile is performed using special software;
- e) ('interpretation of the DNA profile should be performed by two separate persons or by the same person in two moment' different;
- f) the peaks called "stutter" must have an average height not greater than the percentage set by the validation of the kit used for that locus;
- g) all peaks in the electropherogram are to be distinguished from the base line.

SECTION II

Storage times of biological samples and DNA profiles

ART. 24

(Times of storage of biological samples)

1. If DNA extracted from biological samples, after its complete typing it must be destroyed. The destruction operations should be minuted by the staff of the laboratory working.
2. During the phase Ia between the extraction of DNA and its destruction, the operations which preceded the submission of the DNA sample and its location at a controlled temperature in the fridge or freezer must be registered in the LIMS.
3. The part of the biological sample is not used and the second reserve sample shall be retained for a period of eight years.
4. Once the deadline referred to in paragraph 3, the biological samples must be destroyed by the staff on duty at the Central Laboratory. A record of this transaction must be minuted. A record of the destruction must be communicated by telematic AFIS, in order to allow the update of the data relating to the existence of a previous sampling.

ART. 25

(Times for storing DNA profiles)

1. The DNA profiles obtained by the person referred to in Article 9 of the Act shall be kept for thirty years from the date of registration under Article 5, paragraph 1.
2. When the DNA profile refers to persons convicted by final judgment for one or more of offenses for which the law provides for the mandatory arrest in flagrante delicto, or for any of the offenses referred to in Article 407, paragraph 2, letter a) of the Criminal Procedure Code, the period of high conservation is six to forty years after the last registration provided for in Article 5.
3. The DNA profile obtained from a person referred to in Article 9 of the Act in respect of which, at the time of issuance of an irrevocable sentence, was considered a relapse, must be preserved for forty years.
4. In case of a match the DNA profile obtained from a specimen with that obtained from a sample, stored in the database is the only DNA profile obtained from the biological sample under paragraphs 1, 2 and 3 for maximum playing time therein.

CHAPTER V

Duties of the head of the Database and the Central Laboratory and technical professional competent personnel

ART. 26

(Powers of the head of the Database)

1. Responsible for Bank data and data processing in accordance with Article 29 of Legislative Decree 30 June 2003 n. 196, as amended, is the Director of the

Interagency Information System of the Central Directorate of Criminal Police of the Department of Public Security of the Ministry of the Interior.

2. The manager of the database ensures the functionality of the database for the purpose of completeness of the information contained in it and their constant updating and ensure the implementation of all the necessary technical and security, in accordance with the provisions of the code for protection of personal data contained in the Decree of 30 June 2003, n. 196, as amended. II predicted responsible instructs staff referred to in Article 7, paragraph 1, the instructions necessary for the proper operation of the database and perform periodic checks, including sample checks, on the processing operations carried out by police officers, referred to in that article 7 , paragraph 1.

3. The owner of the data of the database in accordance with Article 28 of Legislative Decree June 30, 2003, No. 196, as amended, 6 the Ministry of the Interior - Department of Public Safety.

ART. 27

(Powers of the head of the Central Laboratory)

1. The owner of the Central Laboratory according to Article 28 of Legislative Decree 30 June 2003 n. 196, as amended, 6 the Ministry of Justice - Department of Prison Administration.

2. Responsa bile and the Central Laboratory of the treatment under Article 29 of Legislative Decree 30 June 2003 n. 196, as amended, 6 the Director of the Central Laboratory for the National DNA Data Bank.

3. The head of the Central Laboratory ensures the organization and operation of the Central Laboratory; identifies accredited methods and procedures appropriate techniques for Ia DNA typing as well as the procedures adopted for Ia preservation and destruction of biological samples; identifies the system administrator; identifies specific training courses for the staff of the Laboratory under the Legislative Decree 9 April 2008, n. 81, as amended; predisposes the plan of security and the quality of the Laboratory Manual.

4. The head of the Central Laboratory 6 responsible for the assessment of risks at work, either directly or through the identification of a suitable professional assessment as well as the management of personnel assigned.

CHAPTER VI

Modality and terms of exercise of the powers conferred on the National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV)

ART. 28

(Activities of CNBBSV to ensure compliance with the criteria and technical rules for the operation of Central laboratory and the laboratories that feed)

1. For the finality of Articles 15, paragraph 2, and 16, paragraph 1, letter d) of the Act, the CNBBSV, in quality of oversight body, performs the following activities:

a) it requires the Central Laboratory and workshops that feed it to provide information and produce documents on their organization and how they work;

b) requires the Central Laboratory and workshops that feed specific documentation showing that the activity in reference all'identificazione material / product / matrix are tested for accreditation and that the test methods are accredited according to ISO / IEC 17025 and are undergoing validity, requiring updates of validity of the certificate of quality management system / accreditation of the test;

c) issue, following verification that the method is credited in the course of validity in accordance with ISO / IEC 17025, the clearance to the laboratories of the Police Forces and the institution laboratories highly specialized feeding Ia Database;

d) ensures continuity of participation and Ia Ia capacity to adapt the criteria organized by national or international scientific society of Forensic Genetics of the laboratories of the police and the institution laboratories highly specialized feeding Ia Database;

e) reports to the head of Database Ia non conformity to ISO / IEC 17025 and asks Ia revocation of the inclusion of DNA profiles in the database of the Laboratory concerned;

f) performs, After consulting the Ia for protection of personal data, checks at the Central Laboratory and the laboratories that feed it;

g) performs, using, where necessary, of experts from the Ministry of Health, the inspection and verification activities in the places where they carry out activities relating to identification of the material / product / matrix tested accreditation and methods Accredited testing;

h) reports the outcome of the checks to the Ministries of Interior and Justice and the Authority for the protection of personal data, formulating, when necessary, suggestions regarding the modality of implementation of criteria and technical standards established by law and this Regulation through specific communications and through an annual report.

2. The activities referred to in paragraph 1 are carried out by a college, located within the CNBBSV, composed of at least three components, that performs the

activities referred to in subparagraph g) of the said paragraph 1, making use, where necessary, of experts appointed by the Ministry of Health.

3. Pursuant to Article 15, paragraph 3, of the law, to the members of CNBBSV and experts referred to in paragraph 2 is up, within the limits of the financial resources provided to CNBBSV, it only reimbursement of any costs of the mission documented.

CHAPTER VII

Data erasure and destruction of its biological samples

ART. 29

(Deletion of data and destruction of biological samples in the cases referred to in Article 13, paragraph 1, of the law)

1. The deletion of DNA profiles and destruction of biological samples, in the cases referred to in Article 13 paragraph 1 of the Act, is done with the modality established by special decree of the Ministers of Interior and Justice, heard it for the Guarantor protection of personal data, to be taken within thirty days from the date of entry into force of this Regulation.

2. With it the decree referred to in paragraph 1 shall also governed the modality of entering and updating the data required for the determination of the storage times of DNA profiles, according to Article 25, paragraph 2.

3. The operator of the judicial police in service with it the Department of Public Safety, specifically enabled, provides the combination of personal data and the CUI with it code collection and communicates, via computer, the Central Laboratory en pickup code.

4. The personnel working at it Central Laboratory, specifically enabled, following receipt of the notification referred to in paragraph 3, shall cancel the profile of the DNA present in the database and the destruction of biological samples. Operations to be minuted. II withdrawal code is communicated to the AFIS system in order to allow ('update of the data.

ART. 30

(Deletion of data and destruction of biological samples in the cases referred to in Article 13, paragraph 2, of the law)

1. In the cases referred to in Article 13, paragraph 2, of the law, it laboratory staff of the Police Force performing the identification of the corpse or the discovery of the remains of the corpse or missing person, prior authorization of the Authority judicial proceeding:

a) Cancellation of the DNA profile matched to code biological finding of the corpse, the remains of the corpse, and the relatives of the missing person;

b) the destruction of biological samples of blood relations, whether in his possession;

c) if it is not in possession of biological samples, communicates to the laboratory of the Police Forces who performed the DNA typing of blood relatives ii code finding its biological destruction;

d) communicates, via computer, the AFIS system code sampling 6 that was destroyed in order to allow the upgrade of the data.

2. deile operations referred to in paragraph 1 drawn up 6 minutes.

ART. 31

(Deletion of data and destruction of biological samples in the cases referred to in Article 13, paragraph 3, of the law)

1. In cases under Article 13, paragraph 3, of the law, the police force has not yet proceeded to sending of biologic samples' lab, shall proceed, subject to clearance Judicial Authority, to their destruction and communicates the code to levy AFIS system in order to allow the update of the data.

2. If biological samples have already been sent to the laboratory for typing Ia, Ia Police Force who took the sample communicates AFIS personal data and CUI of the subject. The operator of the judicial police in service at the AFIS system, specifically enabled, provides all'abbinamento of personal data and the CUI with the code removal. II same office communicates to the central laboratory code withdrawal. II staff on duty at the laboratory, specifically authorized, shall cancel the profile of the DNA present in the database, to the destruction of biological samples and communicates the code sample per AFIS system in order to allow the upgrade of the data.

3. Transactions referred to in paragraphs 1 and 2 prepared 6 minutes.

ART. 32

(Cancellation of data and destruction of biological samples referred to in Article 13, paragraph 4, of Law)

1. The profile of DNA 6 automatically deleted from the database of DNA, through a computer application specifics, decors' the terms provided in Article 25.

2. The Database communicates via computer code sample per AFIS system, to allow the update of the data on the collection.

3. The Database communicates via computer code sample per Central laboratory that provides for the destruction of its biologic samples'.

CHAPTER VIII
Final provisions

ART. 33
(Rights)

1. In relation to the processing of personal data in application of this Regulation, the person is entitled to the rights provided for in Article 10, paragraphs 3, 4 and 5 of the Law of 1 April 1981, n. 121, as amended, upon verification of the identity of the same, also, where necessary, by means other than document identification. The rights may be exercised by request addressed to the Department of Public Safety-Central Directorate of Criminal Police of the Ministry of the Interior with which the person concerned has asked, *altresi*, which is given out in the database exercise of the rights referred to in that Article 10 where the data is transmitted to other Member States in cross-border cooperation referred to in Chapter III.

2. The indication referred to in paragraph 1 may be removed at the request of or on decision of the Authority for the Protection of Personal Data of authority or judicial, adopted respectively in accordance with Articles 150 and 152 of Legislative Decree 30 June 2003 n. 196, as amended.

3. Notwithstanding how required under Article 13, paragraph 2, of the law, the relatives of whom *all'articolo* 6, paragraph 1, of this Regulation may, at any time, the Office referred to in paragraph 1, *la* cancellation of their DNA profile acquired under that article 6.

ART. 34
(Equipment of the Data Bank staff)

1. Decree of the Minister of the Interior, in consultation with the Minister of Economy and Finance, to be taken within three months from the date of entry into force of this Regulation, pursuant to Article 5, paragraph seven of Law 1 April 1981, n. 121, *6* determined *la* staffing of the database as part of the budget established by current legislation.

ART. 35
(Transitional provisions)

1. The DNA profiles obtained from biological samples and from biological samples of the subjects at the time of the *levy* fell within the provisions of Article 9 of the law acquired in the course of criminal proceedings before the date of entry into operation of the database are included in the Bank data in accordance with paragraph 2.

2. The authorized under Article 12, paragraph 2, of the law for *l'inserimento* DNA profiles in the database inserts the first level of DNA profiles, with a minimum

number of loci of seven, have been generated before the date of entry into operation of the database. Only DNA profiles, with a number of loci less than ten reared accredited to ISO / IEC 17025 as amended, are inserted, with the prior authorization of the authority competent court, on the second level, notwithstanding how much provided for in Article 10, paragraph 5 of this Regulation.

3. Until the completion of the activities referred to in paragraphs 1 and 2, the profiles stored by police forces at the respective specialized laboratories can be used for investigation purposes at national, prior judicial authorization of the authority.

ART. 36
(Financial coverage)

1. The institution and operation of the database and the Central Laboratory provides you with the resources provided for in Article 32, paragraph 1, of the law and in any case no new or higher charges for it the state budget.

REPORT

With the law 30 June 2009 n. 85, Italy has ratified the Treaty of Prum. I1 Treaty, which is completion of the Schengen Agreement, aimed in particular at strengthening cross-border cooperation in the fight against the phenomena of terrorism, illegal immigration, the international and transnational criminality, discipline and the commitment of the Contracting Parties to create national registers of DNA analysis and exchange the information contained in those databases, the commitment to exchange information on the fingerprint data (fingerprints) as well as access to data entered in the computer files containing the records of vehicle registration.

The Law No. 85 of 2009, ratifying it in the Treaty, is intended, in particular, the establishment of a national DNA database, it at the Interior Ministry, and a central laboratory, it at the Ministry of Justice, with finality of identification perpetrators.

Article 16 of that law states, therefore, that with one or more regulations, adopted pursuant to Article 17, paragraph 2, of the law 23 August 1988, n. 400, shall be governed, in conformity with the principles and guiding criteria laid down by law:

a) its functioning and organization of the National DNA Data Bank and the Central Laboratory for the National DNA Data Bank, the modality of treatment and access via computer and telematics data they collected as well as the modality of communication data and information requests;

b) techniques and modality analysis and storage of biological samples as well as in compliance with the provisions of Article 13, paragraph 4 of Law n. 85 of 2009, the storage time of biological samples and DNA profiles;

c) the functions of the head of the National DNA Data Bank and the head of the Central Laboratory for the National DNA Data Bank as well as the technical and professional skills of the staff assigned to it;

d) the modality and terms of exercise of the powers conferred on the National Committee for Biosafety, Biotechnology and Life Sciences (hereinafter CNBB SV);

e) the modality of cancellation of DNA profiles and destruction of its biological samples in the cases provided for in Article 13 of Law no. 85 of 2009;

f) the criteria and procedures for the removal of DNA profiles and destruction of its biological samples, also as a result of feedback between DNA profiles being tested in order to avoid the conservation, and in the Database in the Central laboratory, ki DNA profiles and more biological samples related to the same subject.

The draft regulation consists of 8 Heads and 36 articles. Chapter I (Art. 1-2) applies to the provisions of a general nature.

With the 'Article 1 defines the' scope of the measure concerning the method of operation and organization of the national database of DNA (the database) and the Central Laboratory for the national database of DNA (the Central Laboratory). Under Article 5 of Law no. 85 of 2009, the database and set it at the Ministry of the Interior, Department of Public Safety, Central Laboratory and while it set it at the Ministry of Justice, Department of Prison, as pin specifically stated in Articles 3 and 4 of the scheme of regolamento.I1 measure also regulates the exchange of DNA data for the purposes of cross-border cooperation referred to in Decisions 2008/615 / JHA and 2008/616 / GA1 of 23 June 2008 concerning ii strengthening cross-border cooperation, particularly in combating terrorism at and cross-border criminality as well as for the purposes of international police cooperation under Article 12 of Law no. 85 of 2009.

Paragraph 3 of Article 1, also points out that it processing of personal data in application of this Regulation and carried out in compliance with the regulations regarding the protection of personal data, in conformity at Code concerning the protection of personal data.

Article 2, with a view to simplifying the text, contains definitions of terms used in the regulation.

II Chapter II (Art. 3-10), divided into 4 sections, concerning the 'functioning of the organization and it Database and the Central Laboratory, the mode of acquisition of biological samples, management and typing of DNA profiles as well as to treatment and access to data.

Article 3, in particular, states that the database and placed it at the Ministry of the Interior, Department of Public Security Service, it Interagency Information System of the Central Directorate of Criminal Police.

In order to enable the collection and its automated comparison of DNA profiles, its software database for the management of DNA profiles and arranged on two levels. The first level and used for investigative purposes at national level. The second level and used in conformity with the decision 2008/615 / JHA and 2008/616 / JHA, as amended, for the purposes of international police cooperation under Article 12 of Law no. 85 of 2009.

It is stated that the continuity of operation of the database and secured by a specific secondary system remotely activated in the event of a disaster or other event of exceptional gravity stated by the head of the database identified by the following Article 26 of the Regulation, the Director of the Service for its Interagency Information System of the Central Directorate of Criminal Police of the Department of Public Security of the Ministry of the Interior.

Access to the database and processing operations data are available only to authorized operators and designated in charge of processing the personal data in accordance with Article 28 of Legislative Decree 30 June 2003 n. 196, according to predefined authorization profiles, meaning by this term all the information uniquely associated with a qualification and a function that needs to access and process the data and information contained in the database. In order to allow verification of the lawfulness of the processing of data, transactions are recorded in special log files that are kept for twenty years. Profiling for authorization, authentication procedures, registration and log analysis, and assigned to a ministerial decree to be adopted heard its Authority for the protection of personal data.

Article 4 concerns the organization and operation of the Central Laboratory it, and which placed it at the Ministry of Justice, Department of Penitentiary Administration - Directorate General of prisoners and treatment.

As for the internal organization, specifying that it has facilities Laboratory robot capable of performing the following steps of DNA typing:

- a) the collection, cataloging and conservation of the biological sample;
- b) set-up of the sample;
- c) possible phase extraction of DNA;
- d) possible quantification stage;
- e) DNA amplification by polymerase chain reaction (PCR), that a chain reaction polymerase enzyme;
- f) reading and interpretation of the DNA profile through automatic sequencer.

On the operation, it is rather clear that the Central Laboratory for the overall management of the flow of work and laboratory data makes use of an information system suitable to manage data and workflow in a laboratory (LIMS) that ensures traceability of the biological sample, the various stages of DNA typing and transactions carried out by staff, including system administrators, and the recording can not be modified by any changes made to the data.

Regarding access to the LIMS Laboratory central planned chegli themselves are available only to authorized operators, according to predefined authorization profiles, following successful completion of an authentication process. Access and

the operations performed on the system LIMS are recorded in special log file can not be modified. Profiling for authorization, authentication procedures, registration and log analysis, and delegated to the inter-ministerial decree art. 3 for the database.

Article 5 regulates the mode of acquisition of biological samples. It is expected that the parties concerned are subject to the levy of two samples of oral mucosa, in order to allow any repetition of DNA typing, following identification of the same via electronic access AFIS (automated system for identifying fingerprints Filing of the central identity of the Ministry of the Interior, Department of Public Safety, placed at the Central Anti-Crime Police State, Scientific Police Service).

The withdrawal is worked by staff in the prison service, specifically trained and trained for this purpose, except for some cases in which ii pickup and performed by the staff of the Police Force delegated to 'run the restrictive measure. These are the cases of application of the order that has the house arrest, stop, or stopped in the act, with the exception of cases in which, after it trial validation, is willing membership in a prison, the application of an alternative measure detention and enforcement of a security measure of imprisonment.

The standard specifies, altresì, the procedure for taking it and subsequent obligations. In particular, it is envisaged that both biological samples are sent at the Central Laboratory in the shortest possible time in a single package the sealed burglary, including through specialized carriers that ensure the integrity of the package itself and its traceability. On each of the samples on purpose identical label must contain, in readable format, a series of default data from the standard itself. It is finally identified the obligations incumbent on the Central Laboratory after receiving the envelope containing the samples (paragraph 7).

In this context it is also governed the situation where DNA typing of the first of the two samples has given a negative result or part, ruling that it informs Laboratory of what the AFIS that, in turn, shall seek to 1'Organo Prosecuting police (office warning) to the repetition of the levy, with the approval of the Authority Judicial.

The repetition of the levy means the destruction of the two biological samples previously acquired as well as the DNA profile subject of a partial typing. Only where it is impossible to proceed to the recurrence of the levy, and allowed to use it according to the biological sample to the activity of DNA typing, however prior authorization Judicial Authority.

Article 6 deals with the procedures to be followed in the event ii biological specimen is acquired, in the course of criminal proceedings, in the case of complaints of missing persons and in case of discovery of corpses and cadaverous remains unidentified. In particular, in cases of complaint of a missing person, the judicial police acquires, where deemed necessary, the information elements of the missing persons and objects to the exclusive use of the same, in order to obtain it DNA profile. To increase it power identification DNA profile, it may also be required to submit voluntarily to the relatives of the biological sampling. For reasons of privacy protection, and predicted that the personal data of those relatives are placed in a subset AFIS available only for the identification of the missing person.

After performing the procedure of typing biological specimen, it staff on duty at the laboratories of the Police Forces on disposal providing power to the Judicial

Authority electronically in the database of the DNA profile, together with the identification data of the same profile.

The rule also governs the situation where the typing of the find was not made by the Laboratory of the Police Forces; in this case the operation is performed by the laboratory staff of the Police Force indicated by the Judicial and the transmission of the DNA profile of the institute of high skill, to this workshop, it takes place according to the rules defined by the inter-ministerial decree art. 3 of the Regulation.

Article 7 establishes the method of feeding the database. It specifies that the database is powered by operators specifically authorized judicial police, on duty at the laboratories of the Police Forces and the Central Laboratory, by inserting electronically DNA profiling and its reference number, code and body code laboratory. Except as required by the provisions on the cancellation of the data in certain circumstances (Article 25, paragraph 4, 29, paragraph 4, 30, paragraph 1, letter a), and 31, paragraph 2 of the Regulation), the further processing of data is allowed the aforementioned personnel in charge of processing the data only for the purposes of matching with the number sequence electropherogram provided by the Laboratory.

Decoding the code levy is, however, carried out by qualified personnel using the AFIS system, specifically enabled for this transaction in ways that allow the tracking of transactions. Personnel enabled the use of the AFIS system is consequently denied access to the system LIMSdei laboratories, as well as the database.

Article 8 is concerned, however, the management of data collected in the Central Laboratory which is allowed only to operators of the judicial police, specifically authorized and appointed with the data processing, in service at the Central Laboratory, with the approval of the Judiciary as required by Article 12, paragraph 2, of Law no. 85 of 2009.

Article 9 states that the current staff at the laboratories Forces Polizie the database, has the power to conduct automated searches by searching and comparison of DNA profiles. Nationally, the consultation may take place only in individual cases and the outcome of the comparison notified to automated laboratories of the police forces who have entered the DNA profile, through the portal of the database.

If the comparison of DNA profiles transmitted and stored in the database give rise to an agreement, the provisions of Article. 10, paragraphs 6 to 9, described below.

The rule, finally, specifies what information must be contained in requests for consultation, in automated responses made through the portal of the database.

Article 10 governs the criteria for inclusion and comparison of DNA profiles and matching rules.

In particular, the DNA profiles are submitted to the database for data collection and comparisons, through the portal of the database. Only DNA profiles validated according to ISO / IEC 17025 can be entered in the database.

As required by Article 3 of this Regulation, the database is structured on two levels. The DNA profiles are entered at the first level of the database from a number of loci of seven. Only the DNA profiles that have a number of loci equal to or exceeding ten are inserted at the second level.

Paragraph 2 states that the CNBBSV can ask the database appropriate documentation regarding the accredited test methods and timing of validity of the certificate sent to the same database from laboratories.

The rule prohibits the transmission to the second level of the database of DNA profiles consist of a mixture of more DNA profiles. If there is such a mingling and is a distinguishable component of the majority by a minority component, it is possible to transmit to the second level of the database of one major component, according to a procedure established by paragraph 5 of the provision in question.

It is also specified the mode of comparison between two DNA profiles in the database that is made on the basis of the loci for which is available in both profiles the same pair of allele values. In order to respond positive correlation between the two DNA profiles, there must be a match of at least ten foci (paragraph 6).

The paragraphs 7, 8 and 9 identify the different levels (total or near match) concordance which constitute the outcome of the operations of comparison of the DNA profiles. It is among other things stated that the outcome of "near match" because there is assessed a match total of at least seven loci profiles examined.

Chapter III (articles 11-18) regulates automated search of the database for purposes of cross-border cooperation and is divided into two sections devoted to the exchange of information for purposes of cross-border cooperation (articles 11-13) and the provisions for the protection policy (Articles 14-18).

Article 11 lists the national contact point for exchanging data for the purposes of international police cooperation in the Service for International Police Cooperation of the Central Directorate of Criminal Police of the Department of Public Safety.

Article 12 regulates the activities of consultation, transmission and comparison of DNA profiles from abroad to Italy. It is expected that the consultation of DNA profiles contained in the database, for the purposes of cross-border cooperation, is allowed to contact points abroad, have the credentials of authentication and authorization, for comparison with DNA profiles contained on the second level the database. The transmission of DNA profiles between the national contact points can be performed in automated mode or second communication channels encoded at international level, ensuring the adoption of appropriate measures, including encryption, to ensure the confidentiality and integrity of data transmitted. The arrangement also establishes the method of notification of the results of the comparison of the profiles, the automated notification and the procedure in case of positive result of the comparison.

Article 13 is concerned, however, the activities of consultation, transmission and comparison of DNA profiles from Italy to foreign countries. In particular, the methods by consulting the data banks abroad by the judicial police who must seek a DNA profile in the international arena, the means of notification of the results of the

comparison of the profiles, the automated notification and the procedure in case of success positive comparison.

Article 14 identifies the scope of the rules contained in the section.

Article 15 specifies that personal data transmitted or received are processed for the purposes of cross-border cooperation referred to in Decisions 2008/615 / JHA and 2008/616 / JHA of 23 June 2008, as well as for the implementation of international agreements executive. The processing of the received data is also recognized for purposes compatible with those for which they were provided and with the authorization of the Member State which transmitted, in accordance with national law.

Article 16 governs the verification of the quality of the data transmitted or received, providing information procedures in case of verification of data transmission inaccurate or should not have been forwarded and assumptions data erasure. If there are reasons to believe that the deletion of data would undermine a legitimate interest of the data subject is a procedure to block, in which the data can be blocked, however, supplied or used solely for the purpose which prevented the cancellation.

Article 17 provides for the verification of the lawfulness of data processing, the registration of the appropriate log file of all transactions conducted for the purpose of cross-border cooperation. The provision lists the information that must be contained in the recordings and the transmission procedures, on request, to the authorities responsible for data protection in the Member State concerned. It emphasizes, finally, that ilog may only be used for purposes of monitoring data protection, including the security profile.

In accordance with Article 18 on the control transmission and reception of personal data for purposes of cross-border cooperation it is exercised by the Authority for the protection of personal data, as provided by the decree of 30 June 2003, n. 196, including a report.

Chapter IV (articles 19-25) regulates the techniques, methods of analysis and storage of biological samples and the time of storage of biological samples and DNA profiles.

Article 19 specifies the types of instruments to be used for the extraction of DNA from biological samples: these are commercial kits commonly used in the scientific community and validated by the forensic scientific literature in terms of yield quantitative and qualitative DNA extracted.

Article 20 provides that the preparation of the sample for the quantification stage, amplification and loaded on automated sequencer can be automated, in order to minimize human error and to have high reproducibility of the data and states the requirements which must have the automated system.

The Article 21 specifies that for the quantification of DNA must be used commercial kits that allow to verify the amount of DNA present in the extract and the presence of possible inhibitors of the enzyme polymerase chain reaction (PCR).

With Article 22 are shown how to follow and the tools to be used for DNA amplification. The arrangement also requires the criteria that must comply with the markers used to define the genetic profile useful for use in identifying personnel. The amplification of every single biological sample must be performed through the

use of two commercial kits for the same locus which have a different sequence of the primers, in order to avoid an incorrect assignment of alleles.

Article 23 indicates the read mode and interpretation of the DNA profile. In particular, it is envisaged that the determination of the genetic profile must be done using an automatic sequencer of nucleic acids for the electrophoresis of the DNA fragments and equipped with software dedicated to the subsequent reading and interpretation of the DNA profile.

The articles 24 and 25 intervene on the issue of time of storage of biological samples and DNA profiles.

According to Article 24, the DNA extracted from biological samples, after its complete typing must be destroyed and the destruction operations should be performed by the staff of the laboratory working. The unused portion of the biological sample and the second sample of reserve should be kept for a period of eight years. After that date, the biological samples must be destroyed by the staff on duty at the Central Laboratory.

Storage times of DNA profiles, according to Article 25, amount to thirty years after the last recording of the identification and removal, referred to in Article 5, paragraph 1, of this Regulation.

The shelf life is increased to forty years if the DNA profile refers to persons convicted by final judgment for one or more of the offenses for which the law provides for the mandatory arrest in flagrante delicto, or for any of the offenses Article 407, paragraph 2, letter a) of the Criminal Procedure Code or in the event that was considered relapse when issuing the sentence irrevocable.

In order to avoid that, for a same subject is stored in Database more DNA profiles, it is specified that in the case of correlation of the profile of the DNA obtained from a specimen with that obtained from a sample, in the databank is only preserved the profile of the DNA obtained from the biological sample, to the maximum provided by the provisions now described.

Chapter V (Articles 26-27) regulates the powers of the head of the Database and the Central Laboratory.

Article 26 identifies the Director of the Interagency Information System of the Central Directorate of Criminal Police of the Department of Public Security of the Ministry of the Interior in charge of the database and the data processing in accordance with Article 29 of Legislative Decree June 30 2003, n. 196. The same ensures the functionality of the database, in terms of completeness of the information and their constant updating, and ensure the implementation of all the necessary technical and security, in accordance with the provisions of the code for data protection personal. The aforementioned responsible instructs staff referred to in Article 7, paragraph 1, of the Regulation the instructions necessary for the proper operation of the database and perform periodic checks, including sample checks, on the processing operations carried out by police officers, referred to in that Article 7, paragraph 1.

It is also specified that the owner of the data processing of the database in accordance with Article 28 of the Code for the protection of personal data is the Ministry of the Interior - Department of Public Safety.

Article 27 states, however, the powers of the head of the Central Laboratory which is located in the Office of the Director of the Central Laboratory for the National DNA Data Bank. The Head of the Central Laboratory competes the organization and operation of the Central Laboratory; the identification of accredited methods, procedures suitable techniques for DNA typing and with those adopted for the retention and destruction of biological samples; the identification of specific training courses for the staff of the Laboratory; the preparation of the plan of safety and quality manual of the laboratory.

The data controller of the Central Laboratory according to Article 28 of the Code for the protection of personal data is identified in the Department of Prison Administration of the Ministry of Justice.

Article 28, inserted in Chapter VI, specifies in detail the terms and conditions with which the CNBBSV ensures compliance by the database, the Central Laboratory and the laboratories of the Police and of the specialized agencies, the criteria and technical standards to be observed in the field. The CNBBSV also exercises a power of suggestion as to the procedures to implement the security measures, the technical guarantees provided, along with any other profiles deemed important.

The provision states, expressly, the gratuitousness of the tasks performed by the members of the National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV) and experts appointed by the Ministry of Health as part of these activities.

Articles 29, 30, 31 and 32, included in Chapter VII, governing the cancellation of data and destruction of biological samples, in the various cases covered by Article 13 of Law no. 85/2009.

In particular, Article 29 regulates the deletion of DNA profiles and destruction of samples biologica followed by final judgment of acquittal, because the offense is not, or because it is not required by law as offense, providing that the arrangements for the cancellation will be defined by a decree of the Ministers of Interior and Justice, after consulting the Authority for the protection of personal data, to be taken within thirty days from the date of entry into force of this Regulation. In this regard it is clarified that the same decree will govern the procedures of entering and updating the data required for the determination of the storage times of DNA profiles, according to Article 25, paragraph 2.

Article 30 regulates the data erasure and destruction of biological samples on missing persons or their relatives in the event of discovery of the persons concerned, or the bodies or the remains of the corpse in case of their identification.

Article 31 rule, then, the data erasure and destruction of biological samples in cases where harvesting operations have been carried out in violation of the provisions of law.

Article 32, finally, governs the data erasure and destruction of biological samples elapsed time of retention of DNA profiles as set forth in Article 25 of this Regulation.

Chapter VIII (Articles 33-36) lays down the final provisions.

Article 33 concerns the right of people to be informed about the processing of data relating to DNA profiles that affect them. In particular, the person is entitled to the rights provided for in Article 10, paragraphs 3, 4 and 5 of Law no. 121 of

1981. The rights may be exercised by request addressed to the Department of Public Safety-Central Directorate of Criminal Police of the Ministry of the Interior.

It is, also, the possibility for the relatives of missing persons who have voluntarily submitted to biological sampling to ask, at any time, the cancellation of their DNA profile.

Article 34 refers to a decree of the Minister of the Interior, in consultation with the Minister of Economy and Finance, the determination of the staffing of the database.

Article 35 bears the transitional provisions, in line with the provisions of art. 17 of Law no. 85 of 2009.

It is expected that the DNA profiles obtained from biological samples and from biological samples of subjects that at the time of the levy fell within the provisions of Article 9 of Law no. 85 of 2009, acquired in the course of criminal proceedings before the date of entry into operation of the database are included in the database. In particular, they are placed on the first level of the database of DNA profiles with at least a number of loci of seven, made before the date of entry into operation of the database. DNA profiles, with a number of loci not less than ten, however, are inserted, with the prior authorization of the competent court, on the second level, without prejudice to the provisions of Article 10, paragraph 5 of the Regulation as regards admixture of profiles.

Finally, it is expected that up to completion of the inclusion of DNA profiles in the database, the profiles stored by police forces at the respective specialized laboratories can be used for investigation purposes at national, prior authorization of the judicial authority.

Article 36, finally, brings together the funding package.

On the draft resolution it has been acquired, pursuant to art. 16 of Law no. 85 of 2009, the favorable opinion of the National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV) and a favorable opinion with observations of the Authority for the Protection of Personal Data (opinion expressed at the meeting of 31 July 2014).

The Guarantor for the protection of personal data has also expressed its understanding on the terms of storage of DNA profiles and biological samples in accordance with art. 13, paragraph 4, of Law no. 85 of 2009.

The comments made by the Guarantor (points 12.1 to 12.8 of the opinion), which "targeted improvements in terms of the articulated" suggested, were accepted almost entirely in the Regulation.

In fact, regarding in particular the observation of point 12.1, in so far as the opinion that "it is necessary to point out that the consultation takes place through the national contact point or foreign", it is noted in the elaborate, both in 'Article 12, paragraph 1, which in Article 13, paragraph 1, explicit

reference to the contact points, the foreign national in the first case and in the second.

With regard instead to the concerns expressed always in 12.1 relatively Article 13, paragraph 1, contains a reference to Articles 7 to 11 of Framework Decision 2008/616 / JHA, it is stressed that this is the result of an editorial choice however, necessary to ensure the completeness of the provision of the law, so much so that about the same Guarantor merely express "concern".

TECHNICAL REPORT

The scheme of regulation lays down measures concerning the operation and organization of the national database of DNA (hereinafter: Database) and the central laboratory for the DNA database (hereinafter Central Laboratory), established by ' Article 5 of Law 30 June 2009, n. 85, and the subsequent enforcement provisions of Chapter II of the Act, with specific reference, in particular, the withdrawal method, management, typing, storing and deletion of DNA profiles of artifacts and biological samples processed by the Bank data. Recca, also, the methods of treatment and access by computer and telematic data collected in the database and the Central Laboratory, in addition to the powers of the head of the Database and the Central Laboratory and the technical and professional skills of the staff.

The draft regulation has been prepared in compliance with the provisions of Article 16, paragraph 1, of the aforementioned Law no. 85 of 2009.

With regard to the effects of a financial pressed that the database set up by the Ministry of the Interior, Department of Public Safety, is allocated as part of the Service for the information system of inter-Central Directorate of Criminal Police, while the recalled Laboratory Central, at the Ministry of Justice - Department of Prison, is allocated within the Directorate General of prisoners and treatment (Polo Rebibbia).

Moreover, for the acquisition of biological samples and typing of DNA profiles of biological samples intended to feed the database, they are interested, in particular, the automated system for identifying fingerprints of the identity of the central records Ministry of the Interior, Department of Public Safety, located at the Central Anti-Crime Department of State Police, forensic service (AFIS), and the laboratories of the science of the State Police and the Carabinieri.

Regarding the establishment and operation of the database and the Central Laboratory, Article 32, paragraph 1, of the aforementioned Law no. 85 of 2009, provides for an allocation of € 11,184,220 for 2008, EUR 6.21 million for 2009, EUR 4.91 million for 2010 and EUR 4.11 million from the year 2011.

The above resources have been allocated to the relevant estimates of expenditure by the Minister of Economy and Finance no. 98388 of 2009. Of the appropriation regime amounted to EUR 4,110,000, 1,827,420 Euros have been allocated to the Ministry of the Interior and the remaining 2,282,580 Euros have been allocated to the Ministry of Justice.

At this appropriation must be added 5.5 million euro arising from the allocation of the Fund only justice, prepared by the Minister of the Interior and

assigned to the Chapter 7391, relating to "Expenditure on the establishment and development of computer systems administration public security "for the financial year 2011 and retained for 2012 on the same item of expenditure.

The resources allocated for the years 2010-2013 (including a scheme with effect from the year 2012 and those from single Justice Fund in fiscal 2011), already allocated to these ministries, allowed to provide the necessary investments for the ' establishment of the database and the Central Laboratory, as well as preparatory activities for the operation of the same, as also the acquisition of hardware, software and services necessary to complete the structures. In addition, the allocation system, mentioned above, allows you to fully implement the provisions of the aforementioned Chapter II of Law no. 85 of 2009, in conjunction with the provisions contained in this draft regulation, which discusses the following items that determine reflections of a financial nature, summarized in the attached summary table of quantification of the costs.

Article 3 regulates the organization, operation and safety measures of the Database. Given that there were no rental costs and maintenance of the facilities, as are used in buildings already available from the Ministry of the Interior, the costs related to hardware, software, services, and the maintenance and guarantees for the institution and the operation of the database, amounted to 3,838,326 euro, (year 2013 included) within the resources allocated to the Ministry of the Interior, the chapter in 2635 and, for 2012, of residue on the chapter of 2011 7391, the management plan 1. Taking into account to ensure that the security measures for the database were incurred charges of around 200,000 euro, it is estimated a cost of 30,000 Euros for the maintenance for the warranty and services, when fully operational, in accordance with the criterion of 15 percent, which will be deducted from the allocation of euro drew 1,827,420 pertaining to the Ministry of 'inside.

Charges laid down in the scheme, relating to the maintenance and system evolution, and to guarantee, also software products, licensing, services, and upgrading hardware, software and networks, were estimated at EUR 575,748.85 representing 15 percent of expenses incurred for the purchase of the equipment up to 2013. The total amount of EUR 605,748 (EUR 575,748 EUR + 30,000 euro) will therefore be distributed in this way: € 327,420 needed to purchase hardware, software and services the cost of which will burden the chapter 7391/1; EUR 278 328 needed for the evolution maintenance and system and to guarantee product software, licenses and services the cost of which will burden the 2635 chapter.

Chapter	Product Description	Anno 2010	Anno 2011	Anno 2012	Anno 2013	Totale
2635	Evolutionary maintenance and systems, security and guarantee for the operation of the IT infrastructure of the BDN DNA	43.263,36	0	0	517.271,29	560.534,65

7391	Purchasing hardware, software, and professional services for IT infrastructure of the BDN DNA	0		3.277.791,04	O	3.277.791,04
Totale complessivo						3.838.325,69
Stima oneri a regime - Importo stimato 15% del totale complessivo						575.748,85
Costi stimati per le misure di sicurezza						200.000
Stima oneri a regime - Importo stimato 15% del totale complessivo					30.000
Quota parte sul capitolo 7391/1						327.420
u o s a p a r t e s u l c a p i t o l o 2 6 3 5						278.328

Article 4 governs the organization, operation and safety measures of the Central Laboratory.

The cost of the initial investment for the construction of the Central Laboratory of structural and systems in a building already in use Penitentiary Administration, amounting to EUR 7,578,164.55, was supported as part of the resources allocated to the Ministry of Justice. E 'in the course of an activity variation in the amount of EUR 515,306.68 and is expected for the current year, the connection to the data network for an estimated amount of € 37,000.00. IT security, was completed in 2014 European race with auction set at 520,000 Euros, awarded December 29, 2014 for a total price of 336,775 Euros. The purchase of office furniture, switchboard and network printers absorbed resources for € 167,849.06. They have been allocated for 3,219,159.56 euro to 16 Provveditorati Regional Prison Administration for the creation and outfitting of the cd "White rooms" within each prison for the sampling of saliva to the prison population. The costs related to system maintenance have been well quantified:

- For maintenance of the building and facilities, the amount is estimated at EUR 157,911.24, approximately 2% of the expenses incurred;
- For office furniture, electronic switchboard and network printers, the amount is estimated at EUR 8,476.38, about 5% of the expenses incurred;
- For the maintenance of the efficiency of the white rooms, the amount is estimated at EUR 162,567.58, approximately 5% of the expenses incurred; for a total, on the total amount spent, amounting to 328,955.20 € (corresponding to 3% of the total in the table).

In view of the scale of the structure (approximately 1,800 square meters), a system will weigh heavy running costs and overheads (cleaning services, utilities, etc.) Currently not quantifiable due to the fact that the Central Laboratory is not fully operational (the entry will be shown in the summary table as "waste").

<i>(euro)</i>						
Chapter	Product Description	Anno 2010	Anno 2011	Anno 2012	Anno 2013	Totale
7300 (Min. giustizia)	Realization of the Central Laboratory for the DNA BDN	3.254.750,48	0	0	36.411,58	3.291.162,06
1752 (Min. giustizia)	Equipment for the operation of the Central Laboratory	0	1.574.557,84 (fondi residui 2010)	0	49.827,00	1.624.384,84
1752 (Min. giustizia)	adaptation electrical room + PV Central Laboratory	0	0	2.662.617,65	0	2.662.617,65
1752 (Min. giustizia)	Office furniture, electronic switchboard and network printers	0	167.849,06	0	0	167.849,06
1752 (MM. giustizia)	Creating and setting up initial white rooms in prisons	0	3.000.000,00	0	219.159,96	3.219.159,96
Totale com lessivo						10.965.173,57
Stima oneri a regime - Importo stimato 3% del totale complessivo						328.955,20
Costi stimati at misure di sicurezza						336.775
Stima oneri a regime - importo stimato 6% del totale complessivo						20.206,5

Article 5 regulates the procedures for acquiring biological sample.

The process of acquisition of the biological sample includes the identification of the subject through a specific application of the AFIS system, or the software already used for the acquisition and collection of fingerprints that has been adjusted in order to accomplish this task, a burden total of EUR 1,923,075, relating to the cost for the realization of a subsystem for the system maintenance, DNA and for the purchase of scanners, readers, printers, etc ..

In relation to this cost, the need for intervention on the AFIS system, the evolutionary maintenance and systems, warranty, supplies comprehensive services consist Code Readers, bars, scanners, thermal printers, was estimated at a total of 288,461 euro, by applying the method of calculation of the 15 percent of the total expenditure incurred.

For the Ministry of Justice, the costs for maintenance of the system are much lower than those estimated by the Ministry of the Interior on the grounds that the

system of Penitentiary does not share data outward matter but only the data dall'AFIS for internal use.

Expenses, operational, within the scope of the budget referred to in Article 32, paragraph 1, of Law no. 85 of 2009.

<i>(euro)</i>						
Capitolo	Descrizione i rodotta	Anno 2010	Anno 2011	Anno 2012	Anno 2013	Totale
2635	Purchasing hardware, software and professional services for adjustment of the AFIS	528.926,40	951.060,00	326.801,57	116.287,05	1.923.075
Totale complessivo						1.923.075
.....Stima. oneri aregime mporto:stimato.15% del totale:complessivo						288.461

<i>(euro)</i>						
Capitolo	Descrizione prodotto	Anno 2010	Anno 2011	Anno 2012	Anno 2013	Totale
1752 (Min. giustizia)	Upgrading machines APFIS to acquire fingerprints and photos signaling	0	1.516.323,60	0	0	1.516.323,60
Totale complessivo						1.516.323,60
Stima oneri a regime - Importo stimato 5% del totale complessivo						75.816,18
1752 (Min. giustizia)	Saliva Kits	0	1.089.000,00	0	0	1.089.000,00
Totale complessivo						1.089.000,00
.....Stima oneri a regime Importo stimato						RESIDUI

Article 6 governs the sampling procedures, management and typing DNA profiling of biological findings acquired in the course of criminal proceedings, and in the case of complaints of missing persons or bodies and family members of people of which must be established that ' identity. To cater to implement these procedures is necessary to have salivary Kit and Kit DNA typing.

Costs incurred to date for the purchase of kits salivary amounted to 1,024,595 euro. The annual fee to be allocated to the purchase of the kits salivary is established every year by sharing demands put forward by individual police forces on the table of inter-bank data.

Costs incurred to date for the purchase of kit DNA typing of biological samples amounted to 1,742,214 euro. The annual fee to be allocated to the purchase

of the kit of DNA typing is determined each year by sharing demands put forward by individual police forces on the table of inter-bank data.

For the costs of operating a system LIMS laboratory, it was taken into account your investment over the period 2010-2013, amounting to 290,376 euro. In view of the forecast of use of ten laboratories of the Police Force, the overall burden to system management LIMS rounded up in about € 300,000, was divided by the number ten laboratories and is therefore estimated at regime A charge of EUR 30,000 for the maintenance of each laboratory, the guarantee and professional services, which will burden the 2635 chapter.

Therefore, the total cost of maintenance regimen of 458 578 Euros, 15% of the amount needed to acquired in the years 2012 and 2013, will burden the Chapter 2635, in the allocation provided for in Article 32, paragraph 1, of the law n. 85 of 2009.

<i>(euro)</i>						
Chapter	Product Description	Anno 2010	Anno 2011	Anno 2012	Anno 2013	Totale
2635	Saliva Kits	230.229,96	0	0	794.365,17	1.024.595,13
2635	KIT typing Finds Biological	1.024.224,48	209.789,49	508.200	0	1.742.213,97
7391	Purchasing hardware, software and professional services for managing laboratories LIMS	0		290.375,70	0	290.375,70
Totale com e lessivo						3.057.184,8
Stima oneri a regime - Importo stimato 15% del totale complessivo						458.578

Article 7 Supply of the database.

There are no additional charges, as already provided for in Article 3.

Article 8 Central Laboratory.

There are no additional charges, as already provided for in Article 4.

Article 9 The procedures for accessing data, comparison of DNA profiles and content of requests and responses to the database.

There are no additional charges, as already provided for in Article 3.

Article 10 identifies the criteria for inclusion and comparison of DNA profiles.

The database is structured on two levels: a first level where I entered all the DNA profiles with a certain quality and can be used at the national level and a second level where they can be inserted only DNA profiles obtained with methods accredited under UNI EN ISO / IEC 17025 in accordance with the technical requirements contained in this draft regulation.

In order to submit DNA profiles in the database, the laboratories of forensic genetics of the Police Force and the establishment of high specialization must then be accredited to EN ISO / IEC 17025. Therefore, given that the cost for the initial accreditation was 2,789,805 euro for the laboratories of the Police Force and for the database, providing for a system should be in operation ten laboratories and

cennato applying the criterion of 15 percent of the initial cost, the cost of

<i>(euro)</i>						
Capitolo	Descrizione prodotto	Anno 2010	Anno 2011	Anno 2012	Anno 2013	Totale

maintaining and certifications accreditation of all laboratories of FF.PP. and the database, nationwide, is estimated at about 418,471 euro.

Therefore, the cost of maintenance of certification / accreditation, operational, recital 10 domestic sites, including the database, is approximately 41 847 euro for sito.I

<i>(euro)</i>						
Chapiter	Product Description	Anno 2010	Anno 2011	Anno 2012	Anno 2013	Totale
2635	Accreditation of Laboratories P. S. and DC	0	805.265,57	1.813.929,68	0	2.619.195,25
7391	Purchasing hardware, software and professional serbizi for certification of BDN DNA	0	0	170.610	0	170.610
Totale complessivo						2.789.805,25
Stima oneri a regime - <u>Importo stimato 15% del totale</u> complessivo						418.471

For the Ministry of Justice, are being activities prior to application for accreditation of the Central Laboratory, handled by specialized company for the contractual amount indicated in the table below. Once you submit your request for accreditation institution Accredia, costs amounted to only the intervention of the national body, around EUR 15,000.00 for the first year and approximately 3,000.00 euro for the next three years, and so via for each time cycle of 4 years.

To these must be added the costs for the maintenance of technical support to accreditation and audit activities. In order to maintain accreditation, it is necessary that the scientific instruments of the Central Laboratory is constantly serviced. Its voice for an estimate of maintenance costs is shown in the table attached to the Articles. 19-24.

1752 (Min. Giustizia)	Agreement with the Department of Biology of the University of Rome "Tor Vergata" for activities related to logistic, provision of scientific instrumentation and reagents, initiating experimental activities for the operation of the Central Laboratory	97.645,15	0	0	33.672,00	131.317,15
1752 (Min. Giustizia)	Professional services for the certification of the BDN DNA				94.550,00	94.550,00
Totale complessivo						225.867,15
..... Stima oneri a regime		Importo stimato 10% del <u>totale</u> complessivo				22.586,71

Articles 11 to 13 contain provisions relating to the various steps necessary for the international exchange of data that require the purchase of special equipment needed for the exchange of security of these data, the expense of which, approximately 244,000 euro, will burden the chapter 7456 / 5. Charges laid down in the scheme, necessary for the maintenance of the equipment mentioned above, were estimated at EUR 36,600, equal to 15 percent of the amount needed to purchase such equipment. The above expenditure will burden the 2635 chapter in the allocation provided for in Article 32, paragraph 1, of Law no. 85 of 2009.

Articles 14 to 18 contain provisions relating to the provisions on the protection of personal data. The security measures are subject to any defined implementations, not quantifiable at present, but which coverage under Article 3. In the latter case the estimate proposal could be subject to change with an annual fee to be allocated established annually by sharing requirements proposed by the Bank data on the table of inter-national database of DNA.

Articles 19 to 24 contain provisions relating to the technological needs of the central laboratory and therefore flow into the portion of the chapter pertaining to the Ministry of Justice.

As for the scientific instruments, the initial investment including LIMS, amounted to more than EUR 3,737,305.54 799,100.00 euro for the purchase of 4 robotic platforms for the automatic puncher and liquid handling. The purchase of reagents for DNA typing accounted for EUR 3,852,640.00. A regime may be necessary to purchase new and better performing laboratory equipment (cost, at present, can not

be quantified), always in the allocation provided for in Article 32, paragraph 1, of Law no. 85 of 2009.

<i>(euro)</i>						
Capitolo	Descrizione prodotto	Anno 2010	Anno 2011	Anno 2012	Anno 2013	Totale
1752 (MM. giustizia)	Purchase of electronic instrumentation and technical furniture + LIMS	3 104 098,80	633.206,74	0	0	3.737.305,54
1752 (Min. giustizia)	Purchase 4 platforms robotizzate for automatic puncher and liquid handling	0	0	0	799.100,00	799.100,00
Totale complessivo						4.536.405,54
1752 (MM. giustizia)	Kit typing biological samples	3.852.640,00	0	0	0	3.852.640,00
Totale complessivo						3.852.640,00
.....Sima oneri a regime - Importo stimato						RESIDUI

Articles 25 to 36 There are no additional charges, as already envisaged as aspects dealt with in other articles of the Regulation.

Article 28 provides that the members of the National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV) and it is up to the experts, within the limits of the financial resources provided to CNBBSV, only the reimbursement of any costs of the mission documented, at the expense of chapter 179 of the Presidency of the Council of Ministers.

In this regard, the competent Office of CNBBSV pointed out that the Committee has its own budget chapter. For the current financial year the budget is equal to € 45,000.00. The CNBBSV has significantly reduced operating expenses as it has activated a web community that allows seamless interaction between the members of the Board, in the absence of meetings in place.

Given the above, operating costs incurred for missions of the members of the Committee have been greatly reduced. The margins to support the mission expenses of the members who will be appointed to monitor the activities referred to in that article 28 is therefore large.

It is, however, that you must keep in mind that - at present - not yet taken any decision on the creation of peripheral laboratories. Where are actually made, it will be necessary to evaluate the number of laboratories actually activated. Only then can it be made a precise quantification of the possible charges to be incurred. Instead, when it is provided only the central laboratory, it can be assumed burden of mission, where all the members appointed are living away from home, for a maximum of two annual inspections.

In the first situation, at present, can be estimated charges for a maximum of € 20,000.00 in the second hypothesis can be budgeted expenses for a maximum of € 7000.00.

Summary table of investment costs and maintenance regime of the database, the Central Laboratory and for the exchange of information of data (Article 32, paragraph 1 of Law 30 June 2009, n. 85). The residual item enter against Article reference, the amount of resources available in the years of reference defined from year to year on the table of inter-national DNA database, and use according to requirements represented by the different administrations. These funds fall under the provision of Article 32, paragraph 1, of Law no. 85 of 2009 on the budget items indicated in this technical report, in the corresponding tables included.

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REPORT TECHNICAL REGULATIONS (ATN)

(All. "A" with the directive of the Prime Ministers of 10 September 2008)

Government proponents: Interior Ministry

Title: Decree of the President of the Republic on "*Measures implementing the Law of 30 June 2009, no. 85, on the creation of the national database of DNA and the central laboratory for the national database of DNA, according to Article 16 of Law no. 85 of 2009*".

Contact: Ministry of Interior

Office of Legislative Affairs and Parliamentary Relations

Office V - Public Safety (06/46547061 - 06/46538308)

PART I. TECHNICAL AND REGULATORY ASPECTS OF LAW

1) Objectives and necessity of regulatory intervention. Consistency with the program government.

Law 30 June 2009 n. 85, in ratifying the Treaty of Prum representing a completion of the Schengen Agreement as regards the strengthening of cross-border cooperation in the fight against the phenomena of terrorism, illegal immigration, international crime and transnational, provided, among other things, in order to identify the perpetrators, the establishment of a national DNA data bank at the Ministry of the Interior, and a Central Laboratory at the Ministry of Justice.

In particular, Article 16 of the aforementioned law provides that, with one or more regulations to be adopted under Article 17, paragraph 2, of the law 23 August 1988,

n. 400, to be regulated in accordance with the principles and guiding criteria laid down by law:

a) the functioning and organization of the National DNA Data Bank and the Central Laboratory for the National DNA Data Bank, the mode of treatment and access via computer and telematics data they collected, and the procedures for communication of data and information requests;

b) techniques and procedures for analysis and storage of biological samples, as well as in compliance with the provisions of Article 13, paragraph 4 of Law n. 85 of 2009, the storage time of biological samples and DNA profiles;

c) the functions of the head of the National DNA Data Bank and the head of the Central Laboratory for the National DNA Data Bank, as well as technical and professional skills of the staff assigned to it;

d) the manner and terms of exercise of the powers conferred on the National Committee for Biosafety, Biotechnology and Life Sciences (hereinafter CNBBSV);

e) the procedures for cancellation of DNA profiles and destruction of its biological samples in the cases provided for in Article 13 of Law no. 85 of 2009;

f) the criteria and procedures to be followed for the deletion of DNA profiles and destruction of the relative biological samples, also as a result of feedback between the DNA profiles object of verification, in order to avoid the conservation, in Database and the Central Laboratory, more DNA profiles and more biological samples related to the same subject.

The provisions introduced by the measure move, therefore, along this direction, which seems to be fully consistent with the government program.

2) Analysis of the national regulatory framework.

The regulatory framework referred to in the decision is made mainly by the provisions set out below:

- Articles. 87 and 117 of the Constitution;
- art. 407, paragraph 2, letter a) Criminal Procedure Code;
- Law 30 June 2009, n. 85;
- Law 23 August 1988, n. 400 (art. 17, para 2);
- Law of 1 April 1981, n. 121;
- Legislative Decree 7 March 2005, n. 82;
- Decree of 30 June 2003, n. 196.

3) Impact of the proposed rules on the laws and regulations. The measure implements the provisions of Law 30 June 2009, n. 85 and without prejudice to other current rules of primary or secondary.

4) Analysis of the compatibility of the intervention with the constitutional principles. It 'been tested for compatibility of the provisions in the measure with constitutional principles.

5) Analysis of the compatibility of the intervention with the powers and functions of the ordinary and special statute regions and local authorities.

The regulatory action is taken in the exercise of the exclusive legislative competence in matters of state in art. 117, paragraph letter. h), of the Constitution. It is therefore fully compatible with the powers and functions of the ordinary regions and special status, as well as local authorities.

6) Check the compatibility with the principles of subsidiarity, differentiation and adequacy as enshrined in Article 118, first paragraph, of the Constitution. It 'been tested for compatibility with the constitutional principles recalled.

7) Do the rilegificazioni and the full utilization of deregulation and simplification of the instruments of legislation. The decree does not contain rules rilegificazione or the use of tools to simplify legislation.

8) Check the existence of bills alleging similar matters before Parliament and its state of the process. They are not presented in Parliament specific bills of material similar.

9) Indication of the lines prevailing case law or the slope of judgments of constitutionality on the same or similar object. They are not recognized, subject, lines prevailing case law or judgments of constitutionality pending.

PART II. THE REGULATORY AND INTERNATIONAL COMMUNITY

10) Analysis of the compatibility of the intervention with European Community rules. The Regulation does not affect the principles and rules of the European.

11) Check the existence of infringement proceedings by the European Commission on the same or similar object. There were no infringement procedures in the specific field of intervention.

12) Analysis of the compatibility of the intervention with the international obligations. Regulatory intervention is aimed at giving effect to international obligations deriving from the ratification of the Treaty of Prum, treaty concluded May 27, 2005 between the Kingdom of Belgium, the Federal Republic of Germany, the Kingdom of Spain, the French Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands and the Republic of Austria on the deepening of cross-border cooperation, in particular to combat terrorism, cross-border crime and illegal migration. The measure also takes into account the decision of the EU Council of 23 June 2008, n. 2008/615 / JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime, and the decision of the EU Council of 23 June 2008, n. 2008/616 / JHA on the implementation of Decision 2008/615 / JHA on the stepping up of cross-border cooperation and the resolution of the EU Council of 30 November 2009, n. 2009 / C 296/01 on the exchange of results of DNA analysis.

13) Indication of the lines prevailing case law or the slope of judgments before the Court of Justice of the European Communities on the same or similar object. There were no lines of the prevailing case law or cases pending before the Court of Justice of the European Union.

14) Indication of the lines prevailing case law or judgments of the slope before the European Court of Human Rights on the same or similar object.

The European Court of Human Rights (ECHR) has had occasion to rule on the use of genetic data banks in the Grand Chamber judgment of 4 December 2008 on the case *S. and Marper vs. United Kingdom*.

With this ruling, the ECHR has affirmed the principle under which the rules of the conservation of genetic data should be inspired by the need to achieve a balanced balance between the need to protect the individual's right to privacy and the need for collective protection order, on the basis, in essence, of proportionality criteria.

15) Possible indications on the lines prevailing regulation on the same subject by other EU Member States.

In adherence to the provisions of the Treaty of Prüm and in the aforementioned decisions of the Council of the European Union n. 2008/615 / JHA and n. n. 2008/616 / JHA and the resolution n. 2009 / C 296/01, the other EU Member States are taking action to adapt their systems.

PART III. ELEMENTS OF QUALITY 'SYSTEMATIC AND DRAFTING OF THE TEXT

1) Identification of new legal definitions introduced by the text, of their need, consistency with those already in use. The measure does not contain new legal definitions, except for those of a technical nature used in scientific language.

2) Verify the correct normative references contained in the project, particularly with regard to subsequent amendments and additions incurred by them.

It 'was the correctness of the reference standards contained in the Decree.

3) Use of the technique of the novel legislation to introduce amendments and additions to existing legislation. The measure is not used to the technique of legislative news.

4) Identification of the effects of implied repeal of the regulatory provisions and their translation rules abrogative expressed in the legal text. The decree does not contain provisions from which implied repeal of other provisions.

5) Identification of provisions of the regulatory applying retroactively or revival of rules previously repealed or authentic interpretation or derogate from the legislation in force.

The decree does not contain provisions applying retroactively or revival of rules previously repealed, nor of authentic interpretation.

6) Check for open proxies on the same subject, also integrating character or corrective.

There are no open proxies on the same subject.

7) Indication of any subsequent measures implementation; check the consistency of the deadlines for their adoption.

The regulatory action provides for the issuing of a decree of the Minister of the Interior, in consultation with the Minister of Justice, for the definition of profiles for authorization, authentication procedures, recording and analysis of log files on which they are Recorded data processing operations of the Bank of DNA data, to be taken within thirty days from the date of entry into force of the Regulation (art. 3, paragraph 9). The decree will define the authorization profiles, authentication procedures, registration and log analysis for access and the operations performed on the system of the Central Laboratory (Art. 4, paragraph 5), the rules for access to the premises and cabinets for the storage of biological samples and electropherograms (Art. 4, paragraph 6), as well the rules for the transmission of the DNA profile of the institute of highly specialized, via computer, to the laboratory identified by the Judicial Police Force (art. 6, paragraph 7).

The legislative measure also provides that the deletion of data and how to enter and update data required for the determination of the storage times of DNA profiles occur in the manner established by decree of the Ministers of Interior and Justice , felt the Guarantor for the protection of personal data, to be taken within thirty days from the date of entry into force of the regulation (art. 29, paragraphs 1 and 2).

Finally, by the Minister of the Interior, in consultation with the Minister of Economy and Finance, to be taken within three months from the date of entry into force of this Regulation, will determine the staffing of the database (art. 34) .

8) Check the full use and updating of data and references statistics relating to the subject matter of the measure, or a statement of the need to commission the National Institute of Statistics with special statistical indication in the report related to the economic and financial sustainability of the related costs.

For the measure in question did not need to resort to special databases or statistical references.

ANALYSIS OF IMPACT OF REGULATORY (AIR)

(Att. To Directive PCM January 16, 2013 - GU12 April 2013, n. 86)

Title: Decree of the President of the Republic on "Measures for implementation Law of 30 June 2009, n. 85 on the creation of the national database of DNA and the central laboratory for the national database of DNA, according to Article 16 of Law no. 85 of 2009 ".

Contact: Ministry of the Interior

Office of Legislative Affairs and Parliamentary Relations

Office V - Public Safety (Tel. 06/46547061 and 06/46538308)

Ministry of Justice

SECTION I: THE CONTEXT AND OBJECTIVES OF REGULATORY

A) The representation of the problem to be solved and critical finding, also with reference to the international and European level, as well as the social and economic needs considered.

The regulatory action aims to implement Article 16 of Law 30 June 2009, n. 85, with which Italy has authorized the ratification of the Treaty of Prüm. The Treaty, which is completion of the Schengen Agreement, aimed in particular at strengthening cross-border cooperation in the fight against the phenomena of terrorism, illegal immigration, international crime and transnational, discipline and the commitment of the Contracting Parties to create national registers of DNA analysis and exchange the information contained in those databases, the commitment to exchange information on the fingerprint data (fingerprints), as well as access to data entered in the computer files containing the records of vehicle registration.

The Law No. 85 of 2009, in ratifying the Treaty, provided, in particular, the establishment of a national DNA data bank at the Ministry of the Interior, and a Central Laboratory at the Ministry of Justice, for purposes of identification perpetrators.

The international and European framework of reference is also the decision of the EU Council of 23 June 2008, n. 2008/615 / JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime, the decision of the EU Council of 23 June 2008, n. 2008/616 / JHA on the implementation of Decision 2008/615 / JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime and the resolution of the EU Council of 30 November 2009, n. 2009 / C 296/01 on the exchange of results of DNA analysis.

The regulatory intervention was aimed at regulating the functioning and organization of the national database of DNA and the central laboratory for the DNA database and the consequent enforcement provisions of Chapter II of Law no. 85 of 2009, with specific reference, in particular, the methods of collection, management, typing, storage and deletion of DNA profiles of artifacts and biological samples processed by the database.

It also wants to adjust the mode of treatment and access by computer and telematic data collected in the database and the Central Laboratory, in addition to the powers of the head of the Database and the Central Laboratory and the technical and professional skills of the staff.

In this sense, regulatory intervention provides an opportunity to introduce, even in Italy, a national DNA data bank, already present in all the other Member States.

At present, in fact, the DNA profiles obtained on the "crime scene" and those taken by persons under investigation are quantifiable in over 50,000 (data of the Police Force); they are kept in the archives of scientific police, set up at:

- Three cabinets forensic State Police (Rome, Naples and Palermo);
- The four Departments Scientific Investigations (RIS) of the Carabinieri (Rome, Parma, Messina and Cagliari).

These law enforcement agencies utilize management systems different profiles and not interconnected.

It affected the ability to perform in terms quick search and comparison data cross both at national and international collaboration in the field of police.

The creation, therefore, a national database only responds to the need to correlate all the information assets of the police forces, accelerating the activities of comparison and research in support of national surveys and speeding also reports cooperation with the police authorities of other countries.

It 'clear that the centralized management of DNA profiles allows management savings compared to the current situation, characterized, as has been said, by a plurality of organizational structures in Italy (technological and human resources). Regulatory intervention also aims at ensuring a better link between the competent authorities at national level in the management of DNA profiles in criminal proceedings.

The regulatory intervention, finally, can overcome some problems in the current system regulated directions.

Provide the "national system" a qualified source of information helps investigators and judicial authorities in the activity of identification of the authors of crimes, both nationally and internationally, even after dozens of years of whether a crime and may be useful to demonstrate the 'innocence of persons indicted for serious crimes. Suffice it to say that, thanks to the comparison of DNA profiles held by the competent national authorities and the British, it has been possible to identify many years after the fact the perpetrator of a murder that took place in 1993.

In general, the ability of different countries to exchange data on DNA profiles allows investigators and judicial authorities to be helped by DNA typing in investigations. Added to this it is that the database is one of the few databases that allow the collection of DNA profiles of missing persons and their relatives to facilitate the recognition phase of cadaverous remains, allowing you to identify the body of a missing person even after years the date of his disappearance.

B) The statement of objectives (short, medium or long term) pursued by the regulatory action.

The project aims to improve the quality of the DNA analysis carried out in criminal proceedings throughout the country by introducing the requirement for laboratories carrying out analysis for the court to use the methods of DNA analysis accredited under the ISO / IEC 17025 by standardizing, in fact, the evaluation and management of DNA profiles.

It is pointed out that the standard ISO / IEC 17025 is adopted by all European countries, so switching to a system that uses it allows you to develop a more effective police cooperation and to make available a given forensic not challengeable on judicial, as commonly accepted (see also Council Decision 2009/905 / JHA).

From this point of view, the advantage to be obtained in the short term is eminently qualitative and obviously, is not susceptible to numerical quantifications.

Added to this is the collection of all the DNA profiles obtained during the criminal proceedings in a national database at the Ministry of the Interior will, as demonstrated by the Member States which use this tool, to increase the power of

identification offenders, especially those in serial character such as theft, robbery, rape.

In the medium to long term benefits can be quantified by referring to its experience in three European countries where for more than ten years was established a unique repository of DNA United Kingdom of Great Britain, the Netherlands and West Germany.

The percentage of cases in which it was possible to identify, thanks to the unique repository, the identity of the person who left a biological trace at the scene of a crime (data provided by the European Network of Forensic Science International - ENFSI):

- 45% in the UK;
- 23% in the Netherlands;
- 17% in Germany.

Therefore, in the medium and long term are expected achievements to those above, warning that Britain is the country's most experienced (and therefore with a batch of data numerically greater - 4.5 million people and 450,000 recorded traces yet identified conserved since 1995). Therefore, a similar result can be achieved only after at least a decade of applying regulatory intervention.

In addition, the ability to collect nationwide also the profile of the DNA of unidentified corpses and the blood relatives of the missing person will facilitate the identification of missing persons and to give an identity to the human remains currently unidentified waiting for an acknowledgment. Currently, the remains of missing persons in Italy are not identified n.1.283 against n.29.763 missing persons yet to trace (data extrapolated from the report June 30, 2014 of the Special Commissioner of the Government for Missing Persons).

The same report shows that the aforementioned 29,763 people missing children are around 15,000, while 1,600 people over sixty-five are suffering from severe neurological diseases.

The creation of a single national repository will significantly improve the ability to identify the bodies "without name".

From this point of view you can not provide a predictive parameter, not being provided a historical term of comparison; therefore the evaluation of the achievement the objective must be evaluated in terms of progressive improvement of identifications.

Among the objectives pursued by the regulatory intervention there is, also, to adhere to the decisions on strengthening cross-border cooperation, particularly in combating terrorism and cross-border crime (cd. Prum decisions), namely to establish a national database DNA also in Italy for forensic purposes, assist in the identification of offenders carried out by Italian people in other Member States (cross-border crime, terrorism) and facilitate the activity is for the prevention of crimes of repression.

C) The description of the indicators that will allow to verify the level of achievement of the objectives set and to monitor the implementation of the intervention as part of VIR.

To monitor the degree of achievement of the objectives set, we will use the following indicators:

- number of DNA samples taken and typed (given annually);
- number of comparisons made (given on an annual basis);
- number of positive concordance observed (given on an annual basis);
- number of missing persons identified through the comparison of DNA samples (given on an annual basis);
- the number of positive or concordances match found in other international databases, at the request of the national police forces;
- the number of positive or concordances match found in the National DNA Data Bank at the request of the governing bodies of European police.

D) A statement of the categories of public and private recipients of the main effects of the regulatory.

Recipients main effects of regulatory are:

- Those requiring removal of the biological sample and listed in Article 9 of Law no. 85 of 2009 - coinciding with persons detained in prisons as a result of final convictions or protective measures - are estimated at approximately 44,000 people (data from the Ministry of Justice, as at February 28, 2015);
- Those involved in the case of a complaint of a missing person or tempering corpses and cadaverous remains unidentified. The "audience" can be quantified in 550 people (the figure coincides with the annual increase of missing persons provided by the Special Commissioner of the Government for missing persons in the aforementioned report of 30 June 2014);
- The public and private laboratories that provide forensic services to the judicial authorities. Currently are accredited to ISO / IEC 17025 two laboratories, one public (University Hospital Careggi (FI), and one private (SIMEF of Reggio Calabria). Added to these are the seven laboratories of the Police Force mentioned above (three police State and four of the Carabinieri). These data are available on the website of ACCREDIA, the national body for accreditation.

SECTION II: CONSULTATION PROCEDURES PRIOR TO THE ACTION

The elaboration of the Regulation has been preceded by the usual consultations with the governments most directly affected by this measure.

No steps were taken to make formal external consultations. This is due to the fact that the art. 16 of Law no. 85/2009 provided for the acquisition on the draft resolution of the opinions of the Authority for the protection of personal data and the National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV), established at the Presidency of the Council of Ministers, that is, of that organ, in a position of independence, are exponential interest of private stakeholders. Although this enough, the possible solutions to be implemented with regulatory intervention were presented during a national conference organized annually by the Association of Italian forensic geneticists (GEFI) and the Italian Society of Human Genetics (SIGU), attended the Office staff of the Interior Ministry directly interested

in the implementation of the National DNA Database. As said, the draft resolution has been acquired, pursuant to art. 16 of Law no. 85 of 2009, the favorable opinion without comment, of the National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV) and a favorable opinion with observations of the Authority for the Protection of Personal Data (opinion expressed at the meeting of 31 July 2014). The Guarantor for the protection of personal data has also expressed its understanding on the terms of storage of DNA profiles and biological samples in accordance with art. 13, paragraph 4, of Law no. 85 of 2009.

The comments made by the Guarantor (points 12.1 to 12.8 of the opinion) were received in the Regulation except for the following:

➤ *the observations referred to in paragraph 12.1 (p. 12 of the draft opinion), concerning Articles. 12, paragraph 2, Section 13, paragraphs 3 and 4.* 'was considered, in fact, that these forecasts, while covering aspects of the exchange of data on foreign states, should set parameters which if not met allow Italy to take no action in requests for data exchange (conditions of admissibility);

➤ *the remark referred to the same point 12.1 in which they are expressed misgivings regarding art. 13, paragraph 1, contains a reference to Articles 7 to 11 of Framework Decision 2008/616 / JHA.* It 'was, in fact, held that the choice pursued by the draft regulation is still necessary to ensure the completeness of the provision of the law;

SECTION III: EVALUATION OF OPTION NOT INTERVENTION OF REGULATORY (OPTION ZERO)

The option of non-regulation did not appear viable, since the measure is adopted in implementation of a specific provision of the law (art. 16 of Law no. 85 of 2009).

The regulatory intervention is necessary, also, to avoid the activation of infringement procedures for failure to implement the decisions on strengthening cross-border cooperation, particularly in combating terrorism and cross-border crime (cd. Decisions Prum) .

Given that these reasons alone are enough to justify regulatory intervention reaffirms - as duly explained in Section I - that the creation, then, of a national database only responds to the need to correlate all the information assets of police, speeding, comparison and research activities in support of national surveys and speeding also relations of cooperation with the police authorities of other countries.

This solution makes it possible to achieve economies of scale and management than the current situation where a plurality of organizational structures in Italy (technological and human resources).

SECTION IV: ALTERNATIVE OPTIONS FOR REGULATORY ACTION

In the course of the activities for the development of regulatory intervention, it was taken into consideration the possibility of providing a single term storage of DNA profiles typed, identified in the statutory maximum (forty years). This option was, however, discarded. It is, in fact, considered to be more consistent with the principles that govern the current regulations regarding the protection of personal data, differentiating periods of retention of DNA profiles, using as parameters

discretivi the type of crime for which the person subjected to collection of DNA itself is definitely convicted and any statement of recurrence art. 99 C.P.

SECTION V: REGULATORY PROPOSAL JUSTIFICATION OPTION AND ASSESSMENT OF ADMINISTRATIVE COSTS AND IMPACT ON SMEs

A) The advantages and disadvantages of the preferred option, for recipients of direct and indirect, short and medium-long term, adequately measured and quantified, also with reference to the possible impact on the organization and activities of public authorities, emphasizing its collective net benefits and their sources of information.

The new regulatory intervention is derived from the results of the technical comparison between the representatives of the various departments responsible for.

The proposed solution will allow to adapt the legal system to the Union and to achieve more effective application of the use of DNA testing in forensic field nationally and internationally.

The regulatory intervention does not entail disadvantages.

In fact, it provides a more rational use of human resources, equipment and financial resources available, overcoming the inevitable redundancies, determined by the fact that mining activities, typing and storage of DNA profiles are made by a number of structures.

In this sense, the solution assumed and also beneficial financially. In this sense indicative procurement activities that it was necessary to carry out parallel processing regulatory intervention in order to ensure the immediate activation of the national DNA database, when completed the 'passage of the measure.

The public procedures carried out to date for the supply of computer equipment and laboratory tests have allowed us to achieve an average reduction of 40% on the unit prices of the price list.

The view to the completion of a single DNA Laboratory and the National DNA Data Bank has also led one of the two accredited laboratories, mentioned in Section I, point D), to conclude an agreement with the regional judicial authorities that brought down costs previously incurred (eg a DNA test has a cost of 19 euro - as extrapolated from the memorandum of understanding signed February 25, 2015).

In addition, regulatory intervention aims to improve the assessment and management of the quality of the results of a DNA test applied in forensics, to simplify and standardize the whole of some technical procedures for the 'credit method of DNA testing in accordance with ISO / IEC 17025, in accordance with the provisions of article 11 of Law no. 85 of 2009, according to which the analysis of data relating to DNA profiling, to be included in the national database of DNA, is performed on the basis of parameters internationally recognized and listed by the European Network of Forensic Science Institutes (ENFSI) , so as to ensure the uniformity of the same.

At Community level, moreover, Article 7 paragraph 4 of Decision 2008/616 / JHA of the European Union provides for the Member States to adopt the necessary

measures to guarantee the integrity of DNA profiles made available to States States and ensuring that these measures comply with international standards, such as EN ISO / IEC 17025.

In this regard, we note that with the construction of the laboratory and the DNA Data Bank and then the irreversible transition to the standard UNI EN ISO / IEC 17025, the forensic data collected in Italy will have a mutual recognition at an international level, an advantage which can not be obtained otherwise given the indications ENFSI.

The establishment of the National DNA Data Bank, also ensure a better link between the competent authorities at national level in the management of DNA profiles in criminal proceedings, will increase the power of identification of offenders and facilitate the ' activities in the event of termination of missing persons and identification of corpses.

B) The identification and estimation of the effects of the preferred option on the micro, small and medium enterprises.

The regulatory intervention has no direct impact on micro, small and medium enterprises. In fact, it caters to the police forces or institutions of higher specialization (currently, as mentioned, only two). These institutions are real centers of excellence and can not obviously be included in the traditional notion of small and medium-sized enterprises.

Regarding the laboratory materials to cater for typing and storage of DNA profiles, please note that these products are now only three US multinationals and German.

C) The indication and the estimated costs of information and related administrative costs, introduced or eliminated against citizens and businesses.

There are no charges to load information from the specified category.

In this regard, the Court finds that the DNA samples are taken from the office staff of the police forces in criminal proceedings. This also applies to withdrawals made for the purposes of identification of missing persons. These activities are carried out not only on cadaverous remains, the family members who voluntarily need to be tested. E 'hardly necessary to point out that such operations are not part of administrative proceedings. They in fact achieve the submission of complaint of missing person and therefore belong to investigations coordinated by the Judicial.

D) The conditions and factors affecting the expected effects of regulatory, which still must be taken into account for the implementation.

There were no conditions or factors that may affect on the immediate implementation of the new regulatory intervention as the current structures are able to operate with the new standards, provided the insurance coverage indicated financial all'art.32 of Law. 85 of 2009.

In this regard, the Department of Public Safety has, since 2012, training programs for the staff of all police forces (with teaching "front" or distance learning) to train a sufficient number of operators to carry the picking operation and DNA typing. These

programs will continue in the coming months and will enable to form, by the end of 2015, total, for different aspects, a total of about 9,000 members of the police forces. Moreover, it has already made for the establishment, within the Department of Public Security, the Ministry of Interior of an ad hoc structure (to be activated within the resources available under current legislation) which has among its aims to provide technical support and information on the operation of the DNA data bank.

It should be noted that by decree of the Minister in consultation with the Minister of Justice, felt the Guarantor for the protection of personal data, to be taken within thirty days from the date of entry into force of the Regulation are defined profiles for authorization, authentication procedures, registration and log analysis, therefore, the aforesaid Decree if not adopted in due time will be conditioning for the timely and proper implementation of the regulatory measure.

SECTION VI: IMPACT ON PROPER OPERATION OF COMPETITIVE MARKET AND COMPETITIVENESS ON 'THE COUNTRY

This regulatory intervention meets the minimum levels required by EU and national legislation. Its incidence is in terms of improved safeguards for the rights of the person, with consequent positive effects on the country's competitiveness at international level, with particular reference to the area of the European Union. The legislation has no impact on the competitive dynamics of the market, since it covers only activities of the judicial police took place in the context of criminal proceedings.

In other words, it does not have some impact on business activity, not bringing it into line with measures to directly or indirectly.

SECTION VII: THE RULES 'IMPLEMENTATION OF REGULATORY INTERVENTION

A) Subjects responsible for implementing the regulatory provisions.

The persons responsible for the implementation of the provisions introduced regulatory intervention are:

- The Ministry of the Interior, for the skills related to the databank of DNA;
- The Ministry of Justice, for the skills related to the Central Laboratory;
- The national contact point at the Ministry of the Interior;
- The laboratories of the Police Force or other institutions highly specialized methods of DNA testing accredited according to ISO / IEC 17025;
- Judicial offices at the Ministry of Justice;
- The Authority for the protection of personal data;
- The National Committee for Biosafety, Biotechnology and Life Sciences (SV CNBB)

B) The actions for advertising and for the information of the operation.

During the year 2014 CNBBSV launched an information campaign at the national level, the benefits to be derived from the establishment of the Laboratory and the DNA Data Bank.

There are no further specific actions for advertising and for the information of 'intervention.

The text will be circulated in the network, through the websites of the Ministry of Interior and Ministry of Justice.

C) Instruments for checking and monitoring regulatory intervention.

The Ministry of the Interior and the Ministry of Justice will follow the execution and the effective implementation of the provisions of the Regulation with direct verification, through its offices concerned, the activities carried out.

Furthermore, the property system to be created within the Department of Public Security (see Section V, letter D)), will verify the data on access to the database to extract the DNA and records of all information on its operation. This activity - performed for the Report to Parliament under Article. 19 of Law no. 85/2009 - permetterà the development of an internal check on the correct use of the aforementioned repository.

In this sense, it will be guaranteed also support the activities of verification and control that is outside the competence of the Authority for the protection of personal data.

D) The mechanisms may be provided for the regulatory review of the assistance.

If developments in science and technology make this necessary, it will update the security measures and arrangements made for the treatment and access to the data collected in the database and the Central Laboratory of Articles 7 and 8, the criteria insertion and comparison of DNA profiles, the matching rules laid down in Article 10, and the method of DNA amplification and reading and interpretation of the DNA profile, set out in Articles 22 and 23.

E) The main priorities to be monitored when implementing the regulatory provisions and considered for VIR.

By the Ministry of the Interior and the Ministry of Justice will be done every two years, the planned VIR, where it will be examined, on the basis of flows statistics provided by the competent internal structures, the degree of achievement of objectives through the indicators in Section I, letter. C).

In particular, the indicator in question will be used to assess the achievement of the objective of:

- in a gradual growth (in absolute or percentage) of the number of entities that they have left a trace on the biological *crime scene*, identified through DNA comparison. In this regard, it will also refer to data broken down because of the types of crimes where it is more frequent recourse to the technique of the comparison of DNA (in particular murder, sexual assault and robbery);

- in a step in a gradual growth (in absolute or percentage) of the number of missing persons identified through DNA comparison carried out by the Laboratory and the Data Bank