ÉTABLISSEMENT FRANÇAIS DU SANG

Objectives and Performance Contract

1 January 2015- 31 December 2018

Approved by the executive board on 19 December 2014

Submitted to the central works council for an opinion on 27 February 2015

Summary

I. Presentation of the French Blood Establishment (EFS)

Scope and role of EFS

The French Blood Establishment (EFS), created on 1 January 2000[1], is the only civilian blood transfusion organization in France. It is a public establishment operating under the supervision of the Ministry of Social Affairs, Health and Women's Rights.

The central aim of EFS is to guarantee France's self-sufficiency in labile blood products (red blood cell concentrates, platelets and therapeutic plasma) in order to meet the needs of patients.

Thanks to the donations made by 1,600,000 voluntary unpaid anonymous donors, more than 550,000 patients received a blood transfusion in 2013. This “ethical” dimension is one of the pillars of the French blood transfusion system.

EFS manages the collection, processing, screening and distribution of labile blood products through its network of 17 regional centers. Each year, EFS collects an average of 10,000 bags of whole blood per day through its 149 permanent collection sites and 40,000 mobile collections.

The donations are transformed into labile blood products at 19 sites, known as “processing platforms”. Processing is the intermediate stage between collection and distribution/issuing. It involves separation of the different blood components, labeling, conservation and packaging.

Since October 2014, donation screening has taken place at four sites in Metropolitan France and three sites in the French overseas departments. Once the results of these analyses have been obtained, the screened products are released to healthcare institutions for distribution.

EFS directly issues to patients around 85% of labile blood products in 156 of its own sites, located in healthcare institutions. The rest of the labile blood products are issued by healthcare institutions from 169 hospital blood banks that are supplied by EFS. Lastly, EFS supplies 443 hospital emergency banks. In total, EFS supplies almost 1500 healthcare institutions (hospitals and clinics) with blood products every day, and also provides counseling for prescribing physicians and users of these products.

As well as distributing labile blood products, EFS supplies plasma to the French Fractionation and Biotechnologies Laboratory (LFB), which manufactures plasma-derived medicinal products.

EFS conserves all the samples of donated blood in a network of blood sample archiving facilities.

The activity of EFS is subject to regulatory and normative requirements, ensuring optimal quality and safety conditions all along the transfusion chain. In addition to the internal checks carried out by EFS, the activities of the establishment are authorized and regularly inspected by the French National Agency for Medicines and Health Products Safety (ANSM).

Together with its core business, EFS carries out other activities, known as associated activities, which make up slightly over 20% of its turnover (11% linked to immunohematology testing):

- The 133 sites providing immunohematology testing, the 17 sites providing HLA (human leukocyte antigen) testing and the 11 sites providing platelet immunology testing within EFS medical biology laboratories carry out tests that are crucial for finding compatible products for transfusions and organ, tissue or cell transplantation(s).
- With 91 health centers providing outpatient medical services (around 75,000 phlebotomies and phlebotomies converted to donations, more than 10,000 therapeutic apheresis

[1] French law No. 98-535 of 1 July 1998 on the reinforcement of health surveillance and the safety of products intended for human use.

procedures, including collection of hematopoietic stem cells for transplantation, and outpatient transfusions), the establishment pursues its public health goals by investing in community-based care.

- In order to support the work of the French Biomedicine Agency (ABM), EFS helps to recruit, inform, receive and register volunteer bone marrow donors. These donors are usually recruited from the population of volunteer blood donors. EFS aims to enroll 18,000 new donors each year on the French Bone Marrow Transplantation Registry (RFGM).
- EFS provides healthcare institutions with products obtained through cell engineering for therapeutic use. EFS is currently responsible for 60% of the activity in this area in France. In order to carry out this work, EFS makes use of 17 platforms where products are frozen/thawed, processed and stored.
- EFS has eight banks for storing substances of human origin (primarily tissues such as corneas, femoral heads, etc.) for patients on the waiting list for a transplant.
- EFS cord blood banks are responsible for the processing, storage and national and international transfer of cord blood products.
- Biological resource centers prepare and store samples of human origin.
- Created in 2004, EFS reagent manufacturing unit prepares the in vitro diagnostic devices required for immunohematology testing for patients and screening of donors. EFS has five manufacturing sites. In order to produce these reagents, EFS also depends on donors, particularly those who have rare blood types or blood types with certain specific features, as red blood cells have a short life and the reagents produced from them can only be stored for a few weeks.
- Finally, EFS produces and delivers blood components or products for non-therapeutic use (laboratory work, education and research).

EFS also carries out cutting-edge research projects with the primary goal of furthering scientific and medical progress for the benefit of patients. These projects demonstrate a strong presence in several key sectors, including the development of advanced technology for the screening and prevention of microbiological risks, cell and tissue engineering and the immunological interface between donors and recipients. In preparation for the future, EFS carries out therapeutic and research activities in areas such as cell, tissue and gene therapy, and since 6 February 2014 it has run the first authorized public pharmaceutical platform for the manufacture of authorized advanced-therapy medicinal products in France. Other EFS pharmaceutical platforms will be set up from 2015.

EFS human resources

EFS can only achieve its goals with the help of its staff members working under both public and private contract, who possess considerable technical knowledge in several areas. At the end of 2014, more than 9500 people were working in the establishment.

EFS staff are mostly health professionals (doctors, biologists or pharmacists, laboratory technicians and nurses), or work in scientific research or support functions.

Human resources policy at EFS is based on:

- social dialogue: EFS values the concepts of openness, dialogue and transparency, and considers its social partners as constructive participants in the life of the establishment;
- a participative approach: the pooling and sharing of experiences are essential for EFS. Dialogue and exchange are made possible through an organization in specialized "networks" (medical affairs, scientific affairs, financial management, etc.);
- appreciation of employees: EFS is committed to developing the careers of its employees by implementing a fair and transparent system;
- commitment to society: EFS is a model of diversity (intergenerational policy, disabled workers, etc.). Health at work is a major concern for EFS.

II. Joint assessment by the French Government and EFS

The Objectives and Performance Contract (COP) 2010-2013 represented a step forward for EFS as it formalized the strategy of the establishment for the first time, after ten years of existence.

In accordance with the commitment made by the French Government and EFS, the previous COP was assessed by the French General Inspectorate of Social Affairs (IGAS) between the end of September 2013 and the beginning of January 2014. The following conclusions were drawn:

Over the last four years, EFS has carried out its mission of providing labile blood products to healthcare institutions under optimal safety conditions

The establishment has guaranteed, at all times and in all places, France's self-sufficiency in labile blood products, including blood with rare phenotypes.

In order to reach this objective, EFS now provides a collection service adapted to the lifestyles of a more urban population. New-generation permanent collection sites known as "Donation Houses" have been set up in the cities. Twelve Donation Houses have been opened in order to recruit and retain blood donors more effectively.

In March 2011 EFS also launched the smartphone app "*Blood Donation*", which is free and accessible to all smartphone users, in order to promote blood donation and make it easier for potential donors to act on their intentions.

Lastly, since 2012, EFS has been running a database covering all donors and blood collection operations. This database can be used to analyze the variations in donations throughout the year, the specific features of the donations and the profiles of donors.

Over the next four years, EFS must continue this reworking of its collection policy and relationship with donors (and make the required organizational changes) in order to strengthen its relevance and efficiency.

At a safety level, epidemiologic surveillance and studies organized by the responsible person have helped EFS to take new risks into account.

EFS has made efforts to improve its efficiency, and these efforts must be continued

The reforms undertaken regarding the different stages of the transfusion chain (particularly donation screening) have reduced the production cost of labile blood products. A greater centralization of purchasing functions has allowed EFS to save €34 million in four years, exceeding the set goal. According to the French General Inspectorate of Social Affairs (IGAS), these initial efforts should be extended to other stages of the transfusion chain, but also to other processes performed by EFS.

At the same time, a number of changes have taken place outside of the establishment which affect its activity: significant and irregular variation in demand for plasma for fractionation to be sent to the French Fractionation and Biotechnologies Laboratory (LFB) and an increase in budgetary constraints on healthcare institutions, which are the consumers of all labile blood products provided by EFS. EFS has been able to cope with most of these issues, but has had greater difficulty anticipating them, especially the drop in hospital demand for labile blood products.

The challenge for the next four years; adapting to future changes in a context of greater instability

EFS must constantly work to meet its targets with the greatest possible efficacy, efficiency and relevance. The social budget restoration goals set by the French president and prime minister have resulted in an even greater demand for efficiency.

In the past few years, EFS has had to cope with a far more irregular growth in demand for labile blood products. The uncertainty regarding the level of transfer (of red blood cell concentrates, therapeutic plasma and plasma for fractionation) is a new variable that must be taken into account in the coming years. The establishment must therefore be more agile in order to effectively adapt to these changes.

Increased competition in the non-monopolistic activities performed by EFS must also be taken into account over the next four years.

In this context of considerable uncertainty, extending the duration of EFS presidential term from three to five years (2012-2017) is clearly helping to ensure greater stability of governance.

The priorities of the public authorities in the area of blood transfusion

The four founding principles (anonymity, charity, free-will and non-profit) must be preserved.

The first priority is adaptation, in the coming years, of blood product supply, in order to guarantee that quantity of blood donated follows closely the changing need for labile blood products and raw materials for the manufacture of plasma-derived medicinal products.

The second priority is the assessment and prevention of transfusion risks linked to transmissible agents, especially emerging agents, enabling the implementation of suitable prevention measures.

The third priority is the necessary evolution of EFS through a strategy of reassessment:

- Reassessment of health safety measures;
- Reassessment of the organization of the transfusion chain.

List of strategic directions

In light of the IGAS report of the new contextual elements and new priorities of the public authorities and EFS, the strategic directions for the period 2015-2018 are:

- Strengthening links with health organizations for the benefit of patients;
- Adapting to the future challenges of self-sufficiency;
- Maintaining a very high level of health safety requirements;
- Strengthening the efficiency of the associated activities;
- Continuing to focus research on the core business;
- Increasing efficiency and guaranteeing the major financial balances of the establishment.

These directions must be completed in the context of the regulatory changes on therapeutic plasma which should take effect during the year 2015[2].

EFS establishment project

This Objectives and Performance Contract was drawn up with the collaboration of the senior management of the establishment. It is a strategic document with the primary aim of establishing reciprocal commitments between EFS and the French Government. It will be completed with an establishment project, which EFS will adopt at the beginning of 2015.

The establishment project will also include specific objectives that are not included in the Objectives and Performance Contract, namely regarding management and human resources. In fact human resources will be considered one of the most important future concerns of the establishment, in order to guarantee efficient completion of its public service missions and adapt to the changing environment.

[2] The decision by the French Council of State of 23 July 2014 led to the reclassification of SD plasma from Labile Blood Product (LBP) to medicinal product. This decision follows the CJEU judgment of 13 March 2014 on this subject, which was imposed on the French authorities. The latter have until 31 January 2015 to adapt French laws and regulations to the EU texts as interpreted by the CJEU. An additional clause may be added to this COP to account for this new legal context, which will affect the activities of EFS.

Objectives and Performance Contract

Between the French Government, represented by the Minister of Social Affairs, Health and Women's Rights and the Minister of Finance and Public Accounts

And the French Blood Establishment,

represented by Mr. François Toujas, President

considering the status of public administrative institution and the missions entrusted to the French Blood Establishment,

after deliberation with the executive board on 19 December 2014,

the following has been agreed:

A performance contract, as described below, has been agreed upon, to cover the period from 1 January 2015 to 31 December 2018.

III. The strategic directions, their objectives and performance indicators

The following strategic directions will determine the actions of EFS over the period 2015-2018.

Strategic direction No. 1
Strengthening links with health organizations for the benefit of patients

EFS plays a key role in the healthcare system and provision of healthcare: it provides and delivers 8700 labile blood products to healthcare institutions every day, in response to prescriber demand.

EFS also performs other activities in collaboration with healthcare institutions:

- immunohematology testing of patients and transfusion counseling;
- care procedures performed in EFS healthcare centers:
- specialized laboratory activities (HLA, HPA, HNA) associated with organ, tissue or cell transplantation;
- processing and storage of cell therapy products.

At a regional level, the creation of Regional Health Agencies (ARS) has significantly modified the organization and regulation of healthcare provision. The agencies are now responsible for piloting public health policy (prevention, surveillance and safety in healthcare) in each region and regulating the provision of healthcare in hospitals and in office-based practices.

Transfusion activities are not yet adequately incorporated in this regional approach to regulating healthcare, but rather are regulated by specific documents (Organizational Models for Blood Transfusion (SOTS)). Furthermore, there is no national policy framework setting out criteria for distributing the activities linked to blood product issuing between healthcare institutions and EFS.

In addition, recent variations in labile blood product transfer, which were not anticipated in time, highlight the need for EFS to improve its capacity for predicting quantitative and qualitative changes in healthcare institutions' needs. Consequently, EFS should not only provide transfusion counseling, but also increase its efforts to ensure correct prescription of labile blood products by strengthening links with health organizations (healthcare institutions, learned societies, the French High Authority on Health (HAS), the French National Agency for Medicines and Health Products Safety (ANSM), the French Institute for Public Health Surveillance (InVS), etc.).

The challenge for EFS over the coming years will therefore be to strengthen the integration of blood transfusion in the public health system, at both a national and regional level, in order to better meet the needs of healthcare institutions and, in the end, the needs of patients.

The following directions will be prioritized:

Objective 1-1
Strengthening EFS involvement in regional healthcare regulation

Government action mechanisms

In the context of the new law regarding the modernization of our healthcare system, the French Government will modify the legal framework so that:

- on the basis of a proposition made by EFS, the Minister of Health can draw up a National Master Plan on Blood Transfusion (SDNTS) specifying the principles and criteria for organizing and distributing blood transfusion activities between EFS and the healthcare institutions (including immunohematology testing linked to the issuing of blood products);
- EFS president can approve, after consultation with the ARS and in the absence of opposition from the Minister of Health, the Regional Organizational Plans for Blood Transfusion (SROTS),

which determine the organization and distribution of blood transfusion activities at a regional level, in accordance with the principles and criteria set out in the SDNTS;

- EFS can participate in the Regional Conferences of Health and Autonomy (CRSA) and in the specialized committee on healthcare organization of the ARS.

Objective 1-2
Better assessment of healthcare institutions' labile blood product needs

EFS must strengthen its capacity:

- to analyze, and if possible forecast in the short term (one year) and medium term (four years) the changes in healthcare institutions' consumption of labile blood products;
- to qualitatively investigate the modifications in healthcare institutions' demand for labile blood products (changes in care structures, changes in medical practices, stricter budget control, etc.).

Joint Government-EFS action mechanisms

- The French Government (DGOS, General Secretariat of Social Ministries and ARS) and EFS will define the development strategy for electronic data exchange (EDE) between healthcare institutions and EFS, in order to:
    - make available a common patient transfusion record, interoperable and regional in the beginning, then eventually national and unique, and applicable across the French territory;
    - implement, without disrupting existing systems that are already largely deployed, a framework for digital trust (including electronic signatures if required) for the prescription of immunohematology tests and labile blood products (LBP), enabling complete digitization;
    - create a unique national identifier for transfused patients.
- In partnership with the French Government (DGOS, General Secretariat of Social Ministries and ARS), EFS will implement a national and regional development strategy for electronic data exchange with healthcare institutions. During the COP period, EFS will implement a tool for monitoring the development of digital relations with healthcare institutions.

Government action mechanisms

- The French Government (DGOS and DSS) will help EFS gain access to the health data held by other institutional bodies (ATIH, CNAM-TS, etc.).

EFS mechanism and action plan

- EFS will implement an action plan in order to:
    - improve the forecasting of healthcare institution's demand for labile blood products This project could begin with an analysis of the factors that lead to transfusion;
    - increase efforts to ensure correct prescription of labile blood products by strengthening links with health organizations (healthcare institutions, learned societies, HAS, competent supervisory agencies, including the ANSM, etc.).

Objective 1-3
Helping to improve the quality and efficiency of the healthcare system in the area of immunohematology testing

The single purpose of immunohematology testing is to guarantee the immunological safety of patients undergoing a transfusion, or the safety of fetuses or newborns in cases of maternal immunization. Recommendations issued in 2011 by a EFS-DGS-DGOS working group highlighted the

importance of bringing pre-transfusion immunohematology testing and labile blood product issuing under a single authority.

Given the importance of immunohematology testing in public health and the high costs involved, the French Government and EFS must explore ways of making this activity more efficient. Efficiency can be improved by limiting redundant recipient immunohematology tests while maintaining a high level of transfusion safety.

Performance indicator

Indicator No. 1	Unit	2014	2015	2016	2017	2018
Number of blood typing/number of labile blood products issued	ratio	1.2	1.18	1.16	1.14	1.1

Methodological specifications: This indicator is still under development.
This indicator, which should be compared with a similar indicator for the number of blood typing in cases where there is no connection between transfusion immunohematology and issuing, should be used to measure the efficiency of the integrated model.

Government action mechanisms

- the French Government (DGOS) will provide EFS with access to data for conducting an analysis of the immunohematology tests performed by EFS and other organizations (including the data available in the CNAM-TS information systems).
- In collaboration with the CNAM-TS, the French Government (DSS and DGS) will examine the conditions for revising the prices of immunohematology tests (especially complex tests).
- The French Government (DGS, DGOS and DSS) will examine the propositions of EFS on the conditions for implementing a companion diagnostic test in the area of immunohematology.

EFS mechanisms and action plans

- EFS will draw up a report on the immunohematology tests performed by EFS and other public and private organizations using data stored in health insurance information systems. On the basis of this report, EFS will suggest to the French government ways in which the organization and conditions for performing immunohematology tests could be changed.
- Together with the healthcare institutions, EFS will study the requirements for better controlling the prescription of immunohematology testing.
- EFS will conduct a study on the benefits and requirements for establishing immunohematology testing as a companion diagnostic test of blood product issuing.
- EFS will carry out feasibility studies and, if necessary, will reorganize its immunohematology testing activities to adapt them to the requirements of each regional blood transfusion center.

Strategic direction No. 2
Adapting to the future challenges of self-sufficiency

Since its creation in 2000, EFS has consistently achieved its self-sufficiency goal, even at times when external events have significantly disrupted the normal operation of the establishment, e.g. during social movements or major climate events.

This self-sufficiency goal is first applied on a quantitative level in order to ensure a sufficient stock of labile blood products to meet recurring needs and minimize risks. Self-sufficiency is also a qualitative goal, as it is important to guarantee a sufficient stock of labile blood products with specific characteristics (e.g. O negative red blood cell concentrates that can be transfused to a large number of patients in critical emergencies, or red blood cell concentrates with phenotypic characteristics that are relatively uncommon in Metropolitan France).

In order to meet its self-sufficiency goal, EFS must also take into account demographic and sociological changes among donors (almost 80% of the population currently lives in urban and peri-urban areas), demographic and sociological changes among recipients (increase in phenotypic diversity of patients who require a transfusion), changes in the prevalence of diseases requiring labile blood products (e.g. diseases that lead to a bone marrow transplant) and changes in prescription practices (professional recommendations).

The following directions will be prioritized:

Objective 2-1
Guaranteeing, under all circumstances, the supply of labile blood products to healthcare institutions on French territory

EFS must keep a 12-day stock of red blood cell concentrates and will aim to balance this 12-day stock over the different blood groups. EFS must inform the Ministry of Health and, if necessary, the Ministry of Overseas France, if the total stock drops below the 10-day level or if, under exceptional circumstances (pandemic, large-scale health emergency, etc.), or during specific periods, the stock level has to be increased significantly beyond the target level.
EFS must also keep a stock of platelet and therapeutic plasma concentrates in order to respond to fluctuations in demand.

Performance indicators

Indicator No. 2	Unit	2014	2015	2016	2017	2018
Number of weeks with red blood cell concentrate coverage levels below 12 days	week	0	0	0	0	0

Methodological specifications: the stock includes work-in-process inventory

Indicator No. 3	Unit	2014	2015	2016	2017	2018
Percentage of bags with phenotypes of interest	%	8.5	8.63	8.75	8.9	9

Indicator No. 4	Unit	2014	2015	2016	2017	2018
Donor satisfaction index	name	8.6	8.3	8.3	8.3	8.3

Methodological specifications: this index is produced by an independent research institute. The objective is to obtain at least the grade obtained in 2013 (8.3).

Government action mechanisms

- The French Government (DGCL and DGS) will support EFS by encouraging blood donation. This will be achieved through focused actions to make collection locations free and accessible, improving knowledge on blood donation among the general public and raising awareness among populations with phenotypic characteristics of high public health value.
- The French Government (DGCL and DGS) will support EFS implantation projects in urban areas.

EFS mechanisms and action plans

- EFS will continue to implement national donation incentive programs in order to recruit and retain blood donors. These programs will be based on a national campaign schedule in order to enhance the synergy between incentive actions and collection services.
- EFS will develop its partnerships with the 2750 voluntary blood donation associations as part of the convention signed with their federation. EFS will strengthen its links with the other collection partners (secondary and higher education institutions, companies, etc.) and its links with associations of labile blood product or plasma-derived medicinal product recipients.

Objective 2-2
Improving the efficiency of collection services and adapting them to sociodemographic changes in the donor population

Performance indicator

At fixed collection sites, reception arrangements for donors and working conditions will guarantee a high level of safety.

Indicator No. 5	Unit	2014	2015	2016	2017	2018
Percentage of whole blood collections performed at fixed sites	%	20	20	21	22	23

Government action mechanisms

- The French Government (DGS and DGOS) will help EFS to make the regulatory changes required to adapt resources to the needs of the establishment (professional qualifications of staff, perpetuation of pre-donation interviews with nurses, etc.).

EFS mechanism and plan of action

- EFS will conduct a feasibility study and reorganize the collection process at fixed and mobile sites in order to:
    - standardize organizations by making them more adaptable;
    - continue to develop efficient collection services through its fixed sites and via the "Donation houses" in order to facilitate donation among urban populations;
    - expand the collection territories.

Objective 2-3
Studying the optimization of apheresis plasma production and developing the framework governing the relationship between EFS and the French Fractionation and Biotechnologies Laboratory (LFB)

Government action mechanisms

- The Government (DGS) will look into implementing a system for regulating the relationship between EFS and the LFB through possible legal and/or regulatory modifications. The

objectives of this system would be improved anticipation of the LFB's needs, a reciprocal multiannual agreement and better distribution of risk.

EFS mechanism and plan of action

- EFS will conduct a study on the optimization of apheresis plasma production

Strategic direction No. 3
Maintaining a very high level of health safety requirements

Transfusion safety measures are introduced in order to ensure control of the whole transfusion chain, from donor to recipient of blood products. The system is essentially based on correct therapeutic indications and compliance with stringent rules and professional recommendations, the implementation of which is regularly assessed and monitored through internal checks (quality and risk management) and external checks (inspections by the French National Agency for Medicines and Health Products Safety (ANSM)). These checks are carried out through an active medical, technical, scientific and vigilance monitoring system.

Over the past few years, EFS has met all its health safety obligations. However, ensuring labile blood product quality and the suitability of blood product characteristics (therapeutic properties/side effects) for patient needs represents a permanent health safety challenge in the area of transfusion.

For two decades, considerable resources have been devoted to transfusion safety. Nevertheless, in the future it is important not to remain focused on the risks that are already "in the limelight" at the expense of less well-known and/or emerging risks. These "new" risks must therefore receive all necessary attention, even in the face of serious budgetary constraints and despite the fact that considerable resources are already committed to transfusion safety.

Over the next four years, EFS will continue its commitment to maintaining a very high level of health safety.

The following directions will be prioritized:

Objective 3-1
Continuing to improve donor and recipient risk prevention

Under the impetus of the French Government, vigilance reporting will continue to develop in the coming years. EFS must take part in this change in order to continue improving the quality of blood products, ensure that they are used correctly and reduce the risks associated with collection and use.

In light of the public health implications, microbiological risk prevention must be analyzed and new measures introduced wherever necessary. Emerging risks and bacterial risks associated with platelet concentrate transfusion are of particular relevance.

The cost-benefit ratio of health safety measures, taken previously or in light of new microbiological or immunological risks, must be assessed by comparison with ratios considered “acceptable” in the area of public health.

Performance indicators

Indicator No. 6	Unit	2014	2015	2016	2017	2018
Highest rate of severe donor adverse events (SDAEs) per 100,000 donations among EFS regional establishments/ Lowest rate of severe donor adverse events (SDAEs) per 100,000 donations among EFS regional establishments	ratio	5	4	3	2	2

Methodological specifications: this indicator is used to measure convergence in donor adverse events reporting, which is under EFS control.

Indicator No. 7	Unit	2014	2015	2016	2017	2018
Proportion of platelet concentrates subject to a new bacterial risk reduction measure	%	12.6	30	>95	100	100

Methodological specification: system implementation depends on previous approval by the authorities and the definition of the funding mechanisms for this measure

Government action mechanisms

- The French Government (DGOS) will implement measures to improve harmonization of reporting practices among healthcare institutions.
- The French Government (DGS) will help EFS to sustain and improve its vigilance system.
- The French Government (DGS) will reexamine the relevance of safety measures, particularly those which have only been implemented in France, by studying the analyses performed by the competent health agencies (including the ANSM) and EFS, and comparing the measures used in France to the measures implemented in other European countries.
- The French Government (DGS and DSS) will check the financial sustainability for EFS of the new heath safety measures that are considered necessary by the competent authorities.

EFS mechanisms and action plans

- EFS will initiate an action plan in order to:
    - harmonize the level of reporting and improve treatment of adverse events, in cooperation with other health bodies (healthcare institutions);
    - implement a single internal tool for vigilance and non-conformity reporting, in connection with quality assurance, in order to better detect weak signals;
    - reorganize its vigilance system on both national and regional levels;
    - continue to strengthen links with regional health safety and vigilance managers, and in particular with Regional Health Agencies (ARS).
- EFS will define and implement action plans for improving management of bacterial risk associated with platelet concentrate transfusion.
- EFS will initiate, during the Objectives and Performance Contract, a medical-economic analysis of current and planned health safety measures, in order to clarify the decision and plan financing of any new measures.

Objective 3-2
Strengthening quality control and therapeutic assessment of labile blood products

Performance indicator

Indicator No. 8	Unit	2014	2015	2016	2017	2018
Assessment of quality control laboratory performance	%	3	2	1	0.5	0

Methodological specifications: this indicator, based on the number of annual atypical results divided by the number of annual participations in Proficiency Testing Schemes (PTSs), will be used to measure improvement in quality control laboratory performance. The acceptable tolerance limits have a target of 0%.

Government action mechanisms

- The French Government (DGS) will support and pass on EFS requests to have representatives participating in the European and international expert groups that define the quality levels required for labile blood products, cell therapy products and advanced-therapy medicinal products.

EFS mechanisms and action plans

- EFS quality control laboratories will become more specialized in order to improve levels of expertise and the overall efficiency of activity.
- EFS will complete the harmonization of control methods used in the quality control laboratories.

Strategic direction No. 4
Improving the efficiency of the associated activities

In addition to its core business, linked to the organization of the transfusion chain, EFS performs other activities, known as "associated activities", which are also managed by other public and private bodies. EFS performs these tasks because it has expert knowledge in the relevant areas (phlebotomy, HLA analysis and tissue and cell engineering), strengthened in some cases through proximity to the core business (production of reagents used for immunohematology testing).

Over the past years, EFS and the French Government have been working to clarify the role of the different health organizations in the associated activities, particularly HLA analyses. EFS has also reorganized its tissue engineering units.

In the coming years, EFS must actively participate, together with the French Government and National Health Insurance Agency, in the processes for strengthening the quality and efficiency of the whole healthcare system. This will affect the activities in the transfusion chain but also the associated activities.

The following directions will be prioritized:

Objective 4-1
Improving the efficiency of the activities shared with other public bodies

Joint Government-EFS action mechanisms

- The French Government (DGS, DGOS, General Secretariat for Social Ministers and ARS) and EFS will conduct a joint regional analysis of the associated activities managed by different public health organizations (geographic location, quality of service, cost of service). The activities involved in this analysis will be:
    - care procedures performed in EFS healthcare centers;
    - specialized laboratory activities associated with organ, tissue or cell transplantation;
    - processing and storage of cell therapy products.
- Based on this analysis and in collaboration with the ARS, EFS and the healthcare institutions will study and implement plans for improving the distribution of these activities.

Government action mechanisms

- The French Government (DGOS), through law or regulation, will clarify the legal framework of EFS healthcare centers.
- In collaboration with the CNAM-TS, the French Government (DSS) will study the conditions for reviewing the prices of procedures performed in healthcare centers, HLA analyses and cell therapy services.

EFS mechanism and plan of action

- Using the studies on the distribution of activities among the different bodies in a single health region, EFS will implement associated action plans to increase the efficiency of the activities under its responsibility.

Objective 4-2
Specifying EFS strategic position for activities in the field of competition

Government action mechanisms

- The French Government (DGS, DSS and DGOS) will examine the possibility of changing the prices of tissues and cells.

EFS mechanisms and action plans

- In collaboration with the French Government (DGS and DGOS), EFS will carry out a strategic analysis of the activities of tissue banks and implement an associated action plan.
- EFS will carry out a strategic analysis of reagent production activities and implement an associated action plan.
- EFS will implement indicators to monitor changes and the associated business model for its activities where competition is allowed.

Objective 4-3
Reorganizing cord blood banks

Merging the cord blood banks should help EFS to improve the quality of its stock of cord blood units while reducing the production costs of this activity, which has been highly unprofitable since subsidies were stopped in 2014.

Performance indicator

Indicator No. 9	Unit	2014	2015	2016	2017	2018
Semi-direct margin of "cord blood" activity	€MM	-1.9	0	0	0	0

Methodological specifications: Turnover plus subsidies minus yearly costs (excluding overhead costs, excluding inventory changes and miscellaneous provisions)

Government action mechanisms

- If the target number of units to be stored is altered, the French Government (DGS, DSS and DGOS) will specify the relevant time frame and financing mechanisms.

EFS mechanism and plan of action

- EFS will implement an action plan for reorganizing the cord blood banks.

Strategic direction No. 5
Continuing to refocus research on the core business

EFS carries out its own research activities, which are recognized by law. This research effort is one of the responsibilities of the establishment in the area of public health and it helps to improve the quality and safety of the transfusion chain as well as scientific and medical progress. These research activities also make the establishment more attractive to health professionals.

During the previous Objectives and Performance Contract, EFS consolidated its research by establishing an institutional certification system, and strengthened its national leadership, resulting in the creation of a research department. EFS, moreover, is focusing on developing partnerships with other public research bodies. At the same time, the creation of an innovation transfer department has helped to protect the results of EFS research, representing a crucial milestone in the result exploitation and technology transfer.

Over the next four years, EFS must continue to structure its research in order to ensure the medium- and long-term viability of its activities.

The following directions will be prioritized:

Objective 5.1
Strengthening co-financing for research activities, technology transfer and research excellence in line with the strategic priorities of EFS

Performance indicators

Indicator No. 10	Unit	2014	2015	2016	2017	2018
Proportion of co-financing obtained via research contracts in partnership with other research or industry bodies in research funding	%	44	45.5	47	48.5	50

Indicator No. 11	Unit	2014	2015	2016	2017	2018
Proportion of the patent portfolio giving rise to a license or licensing option or exploitation by EFS	%	21	22	23	24	25

Indicator No. 12	Unit	2014	2015	2016	2017	2018
% of EFS research teams certified and contracted with EPSTs	%	60	70	80	90	100

Government action mechanisms

- The French Government (DGS) will nominate the members of EFS scientific advisory board.
- As part of the national health strategy, the French Government (DGS) will encourage the alignment of research projects on topics relating to the work of EFS (universities, French public scientific and technological establishments (EPST), French National Alliance for Life Sciences and Health (Aviesan), French National Research Agency (ANR), French Public Investment Bank (Bpifrance), etc.).

EFS mechanisms and action plans

- EFS will set up a scientific advisory board.

- EFS will define and implement an action plan to foster research with outside partners via:
    - an incentive policy aimed at sourcing external financing;
    - a system by which EFS financing is subject to co-certification with universities and/or EPSTs;
    - the extension of its funding program to external teams for topics not covered by EFS teams, such as donation sociology, health economics or industrial processes.
- EFS will define and implement an action plan to encourage high-quality research:
    - by developing its policy of researcher assessment, drawing on the practices of the INSERM;
    - by continuing the bibliometric analysis of the establishment in its different lines of investigation, and broadening this analysis;
- EFS will define and implement an action plan to strengthen its policy of developing the results of studies financed by EFS.

Objective 5.2
Continuing to refocus EFS research on the core business

<u>Government action mechanisms</u>

- The French Government (DGS, DGOS, Ministry of Research) will undertake to improve the coordination of the public bodies responsible for research activities on topics related to the work of EFS, including advanced-therapy medicinal products.

<u>EFS mechanisms and action plans</u>

- EFS will increase investment in the area of clinical research and implement an indicator to assess this effort.
- EFS will ensure that the operating expenditure on platforms for advanced-therapy medicinal products is included in the budget allocated to research.
- EFS will define and produce a bibliometric indicator to show how EFS research activities are being refocused on the core business.

Strategic direction No. 6
Increasing efficiency and guaranteeing the major financial balances of the establishment

In light of the necessary restrictions on public spending and the uncertainty regarding EFS sales activity, for the duration of the current Objectives and Performance Contract EFS will commit to a process of continuous cost optimization in order to maintain its major financial balances in the short and medium term. The natural evolution of costs must be offset by introducing measures for reorganizing the establishment's activity, and harmonizing and sharing practices.

As EFS is unable to meet these challenges alone, the efforts made by the establishment to guarantee the major financial balances must be supported by the French Government, through a reassessment of its revenue if required. Particular attention must also be paid to the funding of health safety measures, given their importance for the establishment.

The results must be used to allocate the necessary resources for meeting current and future medical-technical and economic challenges. In order to do this, the French Government and EFS will review each year requirements for economic equilibrium using multiannual projections prepared by EFS.

The following directions will be prioritized:

Objective 6-1
Adapting the organization and jobs to changes in the environment and the activity

EFS must continue to implement mechanisms for adapting its organization and human resources to respond to changes in the environment and the activity, in order to preserve the major balances of the establishment.

EFS will implement an indicator for monitoring changes in the full-time equivalent (FTE) level of transfusion activity and support functions:

Indicator No. 13 **Rate of growth of activity in WBE units between the estimate *n* and the budget *n+1***	**FTE level growth coefficient for transfusion and support staff for the budget *n+1***
Over 2%	**Negotiation between Government and EFS**
Between 0 and 2%	**Coefficient: 0.3 (over one year)**
Between 0 and -2 %	**Coefficient: 1 (over two years)**
Below -2%	**Negotiation between Government and EFS**

Note 1: a coefficient of 0.3 implies that if the activity in WBE increases by 1%, the workforce must grow by 0.3%.
Note 2: the transfusion process comprises collection, processing, screening, blood sample facility processes, quality control, recipient immunohematology tests, issuing, non-therapeutic uses and trade. Together with support functions, these activities include 90% of EFS workforce.

If the growth in activity is over 2% or under -2%, workforce growth is determined in an *ad hoc* negotiation between the French Government and EFS.

At the same time, EFS will implement a process for monitoring the FTE level of associated activities and research. EFS will also develop indicators for monitoring the productivity of the associated activities and the efficiency of research.

An employment limit will be set for each of these employment categories (transfusion activity and support function on the one hand and associated activities and research on the other hand). This rule excludes modifications to the scope of EFS missions, employment categories considered outside the ceiling, and new health safety measures.

EFS mechanisms and action plans

- EFS will implement the following reorganization projects: continuing the U digital project, merging the cord blood banks, reorganizing the blood sample archiving facilities and streamlining the collection network;
- EFS will implement, if necessary, complementary reorganization or pooling projects, at a national or regional level, particularly in the context of the future establishment project;
- In order to strengthen its efficiency, EFS will undertake to:
  - strengthen the forward planning of jobs and skills;
  - conduct studies on the harmonization of practices and financial management rules and, if required, implement regional or national action plans;
  - present on a yearly basis the workforce distribution (core business, support, associated activities and research) and changes in line with the activity levels.

Objective 6-2
Continuing efforts to optimize all transfusion activity costs

Beyond the efforts made to control staff expenditures, EFS must continue its efforts to optimize the costs associated with the transfusion chain, especially purchases.

Performance indicators

Indicator No. 14	Unit	2014	2015	2016	2017	2018
Growth in transfusion unit cost	%	Between 0 and -2% depending on the level of activity				

Methodological specifications: when activity (expressed as Whole Blood Equivalent) is growing, the establishment will reduce the unit cost of transfusion by 0.5-2% per year:

- growth of between 0.1 and 1%: cost reduction objective 0.5%;
- growth above 1%: cost reduction objective 1.5-2%;
- In the event of negative growth, the establishment will maintain its transfusion unit cost.

Indicator No. 15	Unit	2014	2015	2016	2017	2018
Savings made in purchasing	€MM	4	4	4	4	4

EFS mechanism and plan of action

- EFS will continue its efforts to restrict the cost of purchasing goods and services (36% of total costs in 2013).

Objective 6-3
Guaranteeing the major financial balances of EFS

For prudential reasons, the required yearly self-financing capacity (CAF) of EFS is set at €45 million, before new funding, in order for the establishment to finance investments and operations.

Each year, EFS and the French Government will define the methods to be used to guarantee this sum, on the basis of financial projections and analyses prepared by the establishment.

Performance indicators

Indicator No. 16	Unit	2014	2015	2016	2017	2018
Self-financing capacity (CAF) target value	€MM	45	45	45	45	45

Indicator No. 17	Unit	2014	2015	2016	2017	2018
Level of debt	%	< 30	< 30	< 30	< 30	< 30

Methodological specifications: the financial debt of the establishment cannot exceed 30% of equity while maintaining a maximum ratio of financial costs to gross operating surplus (GOS) of 30%.

Government action mechanisms

- The French Government (DGS, DSS and DB) will examine each year the financial balance conditions of the establishment, particularly prices (labile blood products, immunohematology testing, associated activities, etc.) and specific financing (as a priority of its investments).
  This revision will encompass all parameters: changes in efficiency, in factor cost, changes of the consumer price index, variations in activity and new health safety measures.
- The French Government (DGS, DSS and DB) will issue its assessment for the year *n+1* by the end of October of year *n* at the latest.
- The French Government (DGS, DSS and DB) will confirm its decisions on salary framing before mid-May each year.

EFS mechanisms and action plans

- EFS will provide, at the end of the first half of each year, the measure of performance in transfusion costs, and will provide every year a forecast of a four-year income statement plan, associated with a multiannual investment and financing plan.
- EFS will adapt its financing methods to long-term needs (bank loans, subsidies, sales of assets, etc.) and short-term needs (factoring, etc.).

IV. Reciprocal commitments between the French Government and EFS

The signatories of this performance contract agree on the following reciprocal commitments:

Commitments by the French Government

The French Government undertakes to:

- facilitate all legal or regulatory measures that will help EFS to accomplish its missions, and promptly transmit all necessary information to help EFS to complete its missions effectively;
- involve EFS in the preparation of legal and regulatory provisions that affect it;
- support EFS in its relations with regional health agencies, national agencies, public organizations and ministerial bodies with which the establishment is obliged to collaborate in order to complete its missions;
- organize regular strategic discussions;
- guarantee the presence of all representatives in EFS governing bodies;
- ensure that all directorates or departments are participating in the supervision of the establishment;
- apply the procedures set out in the specific protocol regarding the operational relationship between EFS and the Ministry of Health and revise these procedures wherever required according to feedback.

Commitments by EFS

EFS undertakes to:

- take into account, when preparing its establishment project, the objectives set by law and the public health plans as well as the demands made by the French General Directorate for Health (DGS);
- implement the directions set out in this contract within the set time frames;
- promptly inform the DGS of any problems that could delay or compromise the completion of its objectives;
- take into account, at all levels of its activity, the national policies on public service modernization and improved efficiency of public action;
- support the directorates of the ministry, the regional health agencies, other national agencies and other ministries involved in its missions;
- apply the procedures set out in the specific protocol regarding the operational relationship between EFS and the Ministry of Health.

V. Methods for implementing, monitoring and assessing the Objectives and Performance Contract

Instruments for implementation

The relationship between the French Government and EFS is organized according to protocols developed with the central administration directorates responsible for supervising the establishment.

Annual monitoring of the contract

EFS will produce every year a report on the implementation of the Objectives and Performance Contract, retracing the results achieved in the previous year using the indicators set out in the Objectives and Performance Contract.

After being analyzed by the DGS, this annual report will be discussed in a meeting of a committee dedicated to monitoring the Objectives and Performance Contract.

This annual report, and any amendments to this contract, will be presented to the members of the executive board.

Adjustments

Adjustments can be made in the form of amendments during the execution of this contract.

Final assessment of the contract

A final assessment of the execution of the COP will be performed by the IGAS during the last year of the contract, in accordance with the methods proposed by the DGS, which will be adopted during a meeting between the DGS and EFS.

A summary of this final assessment will be presented to the executive board of EFS.

Signed in Paris on

The French Government, represented by the Minister of Social Affairs, Health and Women's Rights

EFS, represented by its president

The French Government, represented by the Minister of Finance and Public Accounts

VI. Annex 1 - EFS within the French health system

EFS is heavily involved in the French health system and maintains close ties with a number of the associated government bodies. The main bodies that regularly interact with EFS are shown below.

<u>Clients of EFS</u>

Healthcare institutions

Around 1500 public and private healthcare institutions are supplied with labile blood products by EFS. Beyond its role of distribution and issuing, EFS provides transfusion counseling to prescribers. Twenty-four hours a day, seven days a week, it delivers labile blood products adapted to the needs of patients awaiting a transfusion.

The French Fractionation and Biotechnologies Laboratory (LFB)

In France, plasma-derived medicinal products are manufactured by the LFB, from the plasma supplied exclusively by EFS (within its capabilities). This separation of labile blood product processing and stable product manufacture is derived from the first French Health Safety Act of 1993.

<u>Authority supervising the activities of EFS</u>

French National Agency for Medicines and Health Products Safety (ANSM)

Labile blood products fall under the jurisdiction of the French National Agency for Medicines and Health Products Safety (ANSM). EFS is therefore subject to supervision and assessment by this body: its 17 regional establishments are licensed by the ANSM and undergo regular inspections. The ANSM establishes and implements the directions of hemovigilance. It leads and coordinates the actions of the different participants. It receives reports of all severe adverse events in blood donors and all adverse events in recipients of labile blood products, as well as all serious incidents. It is also made aware of all problems that could compromise transfusion safety.

Administrative supervision of EFS

As a national public establishment, EFS is supervised by the Minister of Health, and its main point of contact is the General Directorate of Health (DGS). The broad directions of the establishment are determined by its executive board, whose members include its main supervisors (General Directorate for Health, General Directorate for Healthcare Provision, Social Security Directorate, Budget Directorate, etc.). These directions are defined in this Objectives and Performance Contract. The selling prices of labile blood products are jointly set by the French Minister of Health and Minister of Social Security.

Institutions of the European Union

The institutions of the European Union have the authority to intervene in the area of health, specifically setting quality and safety standards for substances of human origin (blood products, tissues, cells and organs). The European directives define the common minimum standards, but national authorities are free to maintain or establish stricter protection measures.

The European Commission is the main point of contact for EFS, as it is responsible for monitoring the correct implementation of European standards on substances of human origin. It can propose changes to these rules, and also provides financing for transnational projects on health policy and medical research.

Partners of EFS

Representatives of volunteer blood donors

Blood donation, a civic act of solidarity, unites a large number of men and women who strongly believe in the values it represents (charity, free-will and anonymity). The French Voluntary Blood Donors' Association brings together 2750 associations, with a total of almost 750,000 members. It is a long-term partner of EFS and it works every day alongside EFS teams (collection, promotion of donation) and tirelessly advocates the voluntary unpaid donation model. The volunteer blood donor representatives are full members of the EFS executive board.

EFS also relies on a huge number of partners for collections in companies, schools, universities, etc.

Patient representatives

EFS is also in direct contact with a number of associations representing patients who rely on blood products and plasma-derived medicinal products (patients with sickle cell disease, hemophilia, leukemia or immune deficiency, etc.). The patient representatives are full members of the EFS executive board.

French Biomedicine Agency (ABM)

EFS has forged a major partnership with the ABM, an agency that plays a regulation role in organ, tissue and cell transplantation. This close collaboration primarily concerns the recruitment of volunteer bone marrow donors, an activity in which EFS plays a very active role. EFS also performs most of the histocompatibility testing (HLA typing) in order to create “genetic ID cards”.

French Institute for Public Health Surveillance (InVS)

EFS has developed some activities for public health purposes using its expertise, data and biological material. One such example is the work carried out with the InVS as part of a study on flu prevalence among volunteer blood donors.

Furthermore, the InVS analyses epidemiological data regarding the blood donor population.

French National Institute of Blood Transfusion (INTS)

The INTS is a fixed-term French public interest group (GIP) which carries out reference laboratory, research and training activities. EFS owns 35% of its statutory rights. The INTS is accredited by the French Accreditation Committee (COFRAC) for immunohematology reagent batch release on behalf of the European notified bodies.

French High Authority on Health (HAS)

EFS and the HAS have signed a framework agreement with the aim of enhancing scientific knowledge

in the field of transfusion medicine and guaranteeing the safety, quality and correct usage of blood products.

French Army Blood Transfusion Centre (CTSA)

The French Army Blood Transfusion Centre (CTSA) is the military operator that provides transfusion support for the armed forces. As such, it is responsible for collecting blood and blood components in the specific area of units, schools, departments or bodies reporting to the Minister of Defense or public establishments under its authority, and processing, storing and distributing labile blood products required by the armed forces.

In 2015, EFS and the CTSA established a framework agreement between the two entities in order to perform joint or complementary actions.

Partners in research activities

Future activities are designed in the present. This is why EFS allocates around 1.6% of its turnover to financing research activities. It has more than 150 researchers working in 20 mixed research units. Its main partners are research bodies such as the INSERM or the CNRS, as well as universities. Since 2010, EFS has also been an associated partner of the French National Alliance for Life Sciences and Health (Aviesan). This partnership allows EFS, together with other research bodies, to be fully present in strategic areas for its activities and their development.

The Council of Europe

The Council of Europe is an international organization outside the framework of the European Union that brings together 47 countries in the “European region”. The Council of Europe has been active since the 1950s in the field of blood transfusion, and today EFS participates, on behalf of French institutions, in the work of the European Committee on Blood Transfusion (CD-P-TS). This committee manages the updating and annual publication of the Guide to the Preparation, Use and Quality Assurance of Blood Components, a reference tool in Europe and beyond. This work is part of a wider policy of establishing standards and recommendations for guaranteeing optimal quality and safety of blood, its components and derived products.

European Blood Alliance (EBA)

The EBA is an association of non-profit blood transfusion establishments from 23 European countries. The EBA plays a major role in the exchange of knowledge and good practices between transfusion establishments in Europe, the promotion of voluntary blood donation in Europe, and the representation of all its members in the European Institutions. EFS is represented in the association’s board and participates in a number of thematic working groups.

VII. Annex 2 - Protocol of relations between the General Directorate for Health and EFS

The protocol will be drafted after the signing of the COP. This protocol could be structured as follows:

1 - Strategic coordination and functional dialogue between the DGS and EFS
1.1 - Internal organization of the DGS and EFS
1.2 - Bilateral relations
1.3 - Executive board
1.4 - Advisory boards
1.5 - Relationship in a multilateral framework

2 - Methods of cooperation on EFS business activities
2.1 - Request for EFS expertise or technical support
2.2 - Formulation of national legal and regulatory texts
2.3 - Management of disputes
2.4 - EFS participation in European and international action
2.5 - Preparation and managements of alerts and health crises

3 - EFS monitoring arrangements
3.1 - Annual monitoring of the Objectives and Performance Contract
3.2 - Performance and management control

4 - Relationships between EFS and other bodies
4.1 - Relationship with other central administration bodies and with the National Health Insurance Agency
4.2 - Relationship with the Cabinet
4.3 - Relationship with national agencies
4.4 - Relationship with Regional Health Agencies (ARS)

5 - Communication with professionals and the public

6 - Miscellaneous provisions
6.1 - Modification of this protocol
6.2 - Entry into force

VIII. Annex 3 – Multiannual investment plan

All the information included in this annex is the result of simulations performed by EFS using known data in order to clarify the potential future evolution of the economic situation.

The models are therefore based on hypotheses. The results of these simulations serve the single purpose of informing the reader about the different expected impacts and in no way constitute specific commitments.

EFS multi-annual investment plan amounts to €201.7 million over the period 2015-2018 and is broken down as follows:

- real estate needs at a cost of €104.9 million, to be invested in national real estate projects (for which the multiannual sum exceeds €762 thousand) regional real estate projects, renovation and maintenance;
- material needs at a cost of €62.4 million, to be invested in production reorganization projects (blood donation screening, blood sample archiving facilities, etc.), investments in associated activities and research, and renewal and maintenance of biomedical material;
- IT needs at a cost of €29.1 million, to be invested in national IT projects, particularly the completion of the U project, and renewal and maintenance of the national and regional IT infrastructure;
- movable asset investments, vehicles and others at a cost of €5.1 million.

in €K	**P2015**	**P2016**	**P2017**	**P2018**	**TOTAL 2015-2018**
Real estate	25,546	29,599	25,185	24,585	**104,914**
National real estate projects	16,193	16,446	17,927	18,064	**68,629**
Donation houses (real estate only)	132	1,816	810	21	**2,778**
Regional real estate projects	4,857	6,837	1,949	2,000	**15,643**
Miscellaneous real estate	*4,364*	*4,500*	*4,500*	*4,500*	***17,864***
Material linked to activity	16,721	18,832	13,250	13,689	**62,491**
Material for real estate projects (national, donation houses)	1,964	791	100	0	**2,855**
Multiannual equipment investment plan	3,224	4,223	3,445	5,460	**16,352**
Identified material projects	5,452	7,318	3,205	1,729	**17,703**
Miscellaneous material	*6,081*	*6,500*	*6,500*	*6,500*	***25,581***
IT	8,178	7,000	7,000	7,000	**29,178**
National projects	6,000	5,000	5,000	5,000	**21,000**
Identified IT projects	330	0	0	0	**330**
IT for real estate projects (national, donation houses)	110	0	0	0	**110**
Miscellaneous IT	*1,738*	*2,000*	*2,000*	*2,000*	***7,738***
Other	902	1,515	1,398	1,315	**5,130**
Movable assets for national real estate projects	0	80	83	0	**163**
Movable assets, vehicles, miscellaneous	637	935	815	815	**3,202**
Miscellaneous, other	*265*	*500*	*500*	*500*	**1,765**
TOTAL	**51,346**	**56,945**	**46,833**	**46,588**	**201,712**

IX. Annex 4 – COP indicators summary table

	Validated indicator title	Unit	2014	2015	2016	2017	2018
Objective 1-3 Helping to improve the quality and efficiency of the healthcare system in the area of immunohematology testing							
No.1	Number of blood typing/number of labile blood products issued	ratio	1.2	1.18	1.16	1.14	1.1
Objective 2-1 Guaranteeing, under all circumstances, the supply of labile blood products to health care institutions on French territory							
No. 2	Number of weeks with red blood cell concentrate coverage levels below 12 days	weeks	0	0	0	0	0
No. 3	Percentage of bags with phenotypes of interest	%	8.5	8.63	8.75	8.9	9
No. 4	Index of donor satisfaction	Index	8.6	8.3	8.3	8.3	8.3
Objective 2-2 Improving the efficiency of collection services and adapting them to sociodemographic changes in the donor population							
No.5	Percentage of whole blood collections performed at fixed sites	%	20	20	21	22	23
Objective 3-1 Continuing to improve donor and recipient risk prevention							
No.6	Highest rate of severe donor adverse events (SDAEs) per 100,000 donations among EFS regional establishments/Lowest rate of severe donor adverse events (SDAEs) per 100,000 donations among EFS regional establishments	ratio	5	4	3	2	1
No.7	Proportion of platelet concentrates subject to a new bacterial risk reduction measure	%	12.6	30	> 95	100	100
Objective 3-2 Strengthening quality control and therapeutic assessment of labile blood products							
No.8	Assessment of quality control laboratory performance (Number of annual atypical results /Number of annual participations in PTEs)	%	3	2	1	0.5	0
Objective 4-3 Reorganizing cord blood banks							
No.9	Semi-direct margin of cord blood activity	€MM	0	0	0	0	0
Objective 5-1 Strengthening co-financing for research activities, technology transfer and research excellence in line with the strategic priorities of EFS							
No. 10	Proportion of co-financing obtained via research contracts in partnership with other research or industry bodies in research funding	%	44	45.5	47	48.5	50
No. 11	Proportion of the patent portfolio giving rise to a license or licensing option or exploitation by EFS	%	21	22	23	24	25
No. 12	% of EFS research teams certified and contracted with EPSTs	%	60	70	80	90	100
Objective 6-1 Adapting the organization and jobs to changes in the environment and the activity							
No. 13	Growth in number of FTEs for transfusion and support staff according to growth in activity in WBEs	Beyond -2 and +2% activity: negotiation between Government and EFS Between 0 and +2% activity: 0.3 Between 0 and -2% activity: 1					
Objective 6-2 Continuing efforts to optimize all transfusion activity costs							
No. 14	Growth in transfusion unit cost	Between 0 and -2% depending on the level of activity					
No. 15	Savings made in purchasing	€MM	4	4	4	4	4
Objective 6-3 Guaranteeing the major financial balances of EFS							
No. 16	Self-financing capacity target value	€MM	45	45	45	45	45
No.17	Level of debt	%	< 30	< 30	< 30	< 30	< 30

X. Annex 5 - Glossary

ABM	French Agency of Biomedicine
ADSB	French Voluntary Blood Donors' Association
ANR	French National Research Agency
ANSM	French National Agency for Medicines and Health Products Safety
ARS	French Regional Health Agency
ATIH	French Technical Agency for Information on Hospitalization
Aviesan	French National Alliance for Life Sciences and Health
BPI	French Public Investment Bank
EB	Executive Board
CSS	Capacity for Self-Sufficiency
EC	Ethics Committee
RBCC	Red Blood Cell Concentrate
CICE	French Tax Credit for Competitiveness and Employment
CNAM-TS	French National Health Insurance Agency for Wage Earners
CNP	French National Steering Council
CNRS	French National Center for Scientific Research
TNC	Total Nucleated Cells
COFRAC	French Accreditation Committee
COP	French Objectives and Performance Contract
CRSA	French Regional Conference of Health and Autonomy
CSP	French Public Health Code
DB	French Budget Directorate
DGCIS	French General Directorate for Competitiveness, Industry and Services
DGCL	French General Directorate for Local Authorities
DGOS	French General Directorate for Healthcare Provision
DGS	French General Directorate for Health
DSS	French Directorate of Social Security
GOS	Gross Operating Surplus
EDE	Electronic Data Exchange
PTS	Proficiency Testing Scheme
EFS	French Blood Establishment
SDAE	Severe Donor Adverse Event
EPA	French public administrative institution
EPIC	French industrial and commercial public institution

EPST	French scientific and technological public institution
WBE	Whole Blood Equivalent
FTE	Full Time Equivalent
HAS	French High Authority on Health
HLA	Human Leukocyte Antigen
HPA	Human Platelet Antigen
HNA	Human Neutrophil Antigen
IGAS	French General Inspectorate of Social Affairs
IH	Immunohematology
INSERM	French National Institute of Health and Medical Research
INTS	French National Institute of Blood Transfusion
InVS	French Institute for Public Health Surveillance
LFB	French Fractionation and Biotechnologies Laboratory
OJ	Official Journal
PLTR	Products for use in Laboratories, Teaching and Research
PLFSS	French Social Security Financing Bill
MYFP	Multiannual Financing Plan
MYIP	Multiannual Investment Plan
LBP	Labile Blood Products
BDS	Blood Donation Screening
RFGM	French Bone Marrow Transplantation Registry
SDNTS	French National Master Plan on Blood Transfusion
SG MAS	French General Secretariat of Social Affairs Ministries
SOTS	Blood Transfusion Organization Plan
SROTS	Regional Blood Transfusion Organization Plans
CBU	Cord Blood Unit