



The EU Framework Programme for Research and Innovation

HORIZON 2020

Initiatives under Article 185 TFEU:

Legal framework and main specificities

Madrid, 1 July 2016



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Legal basis in TFEU

Article 185 TFEU

"In implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes."

- European Parliament and Council decide by ordinary legislative procedure
- the Economic and Social Committee is consulted
- ☞ *the participating Member States (pMS) are the driving force*

Legacy

Van Velzen review recommendations for Article 185 initiatives on the basis of the July 2007 report in the context of EDCTP under FP6

- Existence of **clearly defined national research programmes to be implemented jointly**
- Clear **commitment of the participant Member States** to support financially and politically the joint implementation
- Clear **arrangements on the funding mechanisms** ensuring the **selection of proposals on the basis of scientific excellence**
- Existence of an efficient and autonomous **Dedicated Implementation Structure (IS)**
- Clear **division of responsibilities and liability between Commission and the IS**

General Financial Regulation (FR) specificities for Article 185 initiatives (Regulation 966/2012 as amended by Regulation 1929/2015, see also Commission Delegated Regulation 1268/2012 (RAP) as amended by Delegated Regulation 2462/2015)

Methods of implementation of the budget: Article 58 FR

1. The Commission shall implement the budget in the following ways:

...

(c) **indirectly** ('indirect management'), ... by entrusting budget implementation tasks to:

...

(vi) bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

...

2. The Commission remains responsible for the implementation of the budget ...

Indirect management: Article 60 FR

1. Entities and persons entrusted with budget implementation tasks pursuant to point (c) of Article 58(1) shall respect the principles of sound financial management, transparency and non-discrimination and shall ensure the visibility of Union action when they manage Union funds. They shall guarantee a level of protection of the financial interests of the Union equivalent to that required under this Regulation when they manage Union funds ...

2. ... entities and persons ... shall ...:

- (a) set up and ensure the functioning of an effective and efficient internal control system;
- (b) use an accounting system that provides accurate, complete and reliable information in a timely manner;
- (c) be subject to an independent external audit, performed in accordance with internationally accepted auditing standards by an audit service functionally independent of the entity or person concerned;
- (d) apply appropriate rules and procedures for providing financing from Union funds through procurement, grants, prizes and financial instruments, including the obligations set out in Article 108(12);
- (e) ensure, in accordance with Article 35(2), the ex post publication of information on recipients;
- (f) ensure a reasonable protection of personal data, as laid down in Directive 95/46/EC and Regulation (EC) No 45/2001.

Ex ante assessments and delegation agreements: Article 61 FR

H2020 Framework Programme specificities for Art. 185 initiatives (Regulation 1291/2013)

"public-public partnership": a partnership where public sector bodies or bodies with a public service mission at local, regional, national or international level **commit with the Union to jointly support the development and implementation of a research and innovation programme or activities** (Article 2(5) FP)

Public-public partnerships may be supported... through: Article 26(2) (b) FP

(b) Union participation in programmes undertaken by several Member States in accordance with Article 185 TFEU where the participation is justified by the scope of the objectives pursued and the scale of the resources

... such initiatives shall only be proposed in cases where there is a need for a dedicated implementation structure and where there is a high level of commitment of the participating countries to integration at scientific, management and financial levels.

Proposals are identified based on all of the following criteria: Article 26(2) FP

- (a) **Clear definition of the objective** to be pursued and its relevance to the objectives of H2020 and broader Union policy objectives
- (b) **Indicative financial commitments of the participating countries, in cash or in kind, ...**
- (c) **Added value of the action at Union level**
- (d) **Critical mass**, with regard to the size and the number of programmes involved, the similarity or complementarity of activities and the share of relevant research they cover
- (e) **Appropriateness of Article 185 TFEU for achieving the objectives**

H2020 Specific Programme specificities for Article 185 initiatives (Decision 743/2013)

Annex I - Common elements for the indirect actions

...

3. PARTNERING

Existing public-public partnerships may receive support from H2020, provided they address H2020 objectives, contribute to realising the ERA, meet the criteria laid down in Horizon 2020 and have shown to make significant progress under FP7.

Initiatives under Article 185 TFEU supported under the FP6, and/or under the FP7 for which further support may be provided under the above conditions include:

- the European & Developing Countries Clinical Trials Partnership (EDCTP),
- Ambient Assisted Living Joint Programme (AAL),
- Baltic Sea Research and Development Programme (BONUS),
- the Eurostars Programme,
- the European Metrology Research Programme (EMRP).

Further public-public ... partnerships may be launched under Horizon 2020 where they meet the defined criteria.

- *Basis for launching other, new Art. 185 initiatives*

H2020 Rules for Participation

(Regulation 1290/2013)

A coherent set of rules: Article 1(1) and 1(2) RfP

[Same as for JUs]

1. This Regulation lays down specific rules for participation in indirect actions undertaken under Regulation (EU) No 1291/2013, including participation in indirect actions funded by funding bodies ...

This Regulation also lays down the rules governing the **exploitation and dissemination of results**.

2. Subject to the specific rules laid down in this Regulation, the relevant rules of FR and RAP shall apply.

-> The coherent set of rules for Art. 185 initiatives is a major difference from FP7

Derogations for Article 185 initiatives: Article 1(3) RfP Cf. Article 38(1) RfP

Article 1(3) RfP

❖ ... any basic act which entrusts budget implementation tasks to a funding body under Article 185 TFEU may establish rules which depart from those laid down in this Regulation.

-> *Derogations are included in the EP & Council decisions establishing the Article 185 initiatives*

-> *No delegated acts*

Cf. Article 38(1) RfP: Participant Guarantee Fund (PGF)

A participant guarantee fund (the "Fund") is hereby established and shall **cover the risk associated with non-recovery of sums due to the Union under actions financed through grants** by the Commission under Decision No 1982/2006/EC and **by the Commission or Union funding bodies under "Horizon 2020"** according to the rules set out in this Regulation. The Fund shall replace and succeed the Participant Guarantee Fund set up under Regulation (EC) No 1906/2006.

-> *PGF does not cover legal forms of funding bodies other than Union bodies.*

Specificities for Art. 185s: Article 2(1)(11) and 2(1)(22) RfP

[Same as for JUs]

(11) 'funding body' means a **body or authority, other than the Commission, as referred to in point (c) of Article 58(1) of FR, to which the Commission has entrusted budget implementation tasks ...**

In most cases, RfP refer to "Commission or the relevant funding body"

- If not, need for interpretation, e.g. ethics review

(22) 'work plan' means the **document similar to the Commission work programme adopted by funding bodies ...**

- Similar in function and in content, e.g. call management rules of General Annexes to the H2020 Work Programme

In most cases, RfP refer to "work programme or work plan"

- If not, need for interpretation, e.g. **Article 10(1) Eligibility for funding:**

1. The following participants are eligible for funding from the Union:

...

(c) any legal entity established in a **third country** identified in the **work programme** (i.e. not work plan)

- **Important provision (that can be) used by Art. 185 IS:**

Article 9(5): **Where appropriate and duly justified**, work programmes or work plans may provide for additional conditions according to **specific policy requirements** or to the **nature and objectives of the action**, including inter alia conditions regarding the number of participants, the **type of participant** and the place of establishment.

Decisions on Article 185 initiatives (basic acts)

- Decision 554/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in the **Active and Assisted Living Research and Development Programme** jointly undertaken by several Member States -> **AAL 2**
- Decision 556/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a **second European and Developing Countries Clinical Trials Partnership Programme (EDCTP 2)** jointly undertaken by several Member States
- Decision 555/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a **European Metrology Programme for Innovation and Research (EMPIR)** jointly undertaken by several Member States
- Decision 553/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a Research and Development Programme jointly undertaken by several Member States aimed at **supporting research and development performing small and medium-sized enterprises** -> **Eurostars 2**

With regard to **FP6** and **FP7**:

- **AAL**, **EDCTP**, **EMRP** and **Eurostars** receive new funding

H2020 Article 185 TFEU initiatives funded:

- **AAL 2**, **EDCTP 2**, **EMPIR**, **Eurostars 2** (4 initiatives)

H2020 Article 185 TFEU initiatives budget: ~1.5 Bn €, i.e. approximately 2% of H2020 FP budget.

Main additional common features in Article 185 decisions

- Each initiative under Article 185 established by **Decision of the European Parliament and of the Council: Main part** and Annexes, mainly on **Objectives, Implementation, Governance**
 - ✓ **List of Participating States (pS)**
 - ✓ **EU contribution and contributions from pS**
 - ✓ Conditions, e.g. establishment of an IS, programme implementation
 - ✓ **Ex-post audits:**
 - ✓ by the **IS** or the **national programme management agencies/national funding bodies**
 - ✓ Commission may decide to carry them out itself
 - ✓ **Protection of financial interests of the Union**
 - ✓ audits by the Commission, Court of Auditors
 - ✓ investigations, including on-the-spot checks and inspections by OLAF
 - ✓ **Annual work plan**
 - ✓ Draft annual work plan to be approved by the Commission before its adoption by the IS.

Main features in Article 185 decisions - Participation

Initiatives	Participating States	Who may become a Participating State
AAL 2	16 MS	- Any other MS or AC
EDCTP 2	14 MS + 1 AC	- Any other MS or AC
EMPIR	23 MS + 4 AC	- Any other MS or AC
Eurostars 2	28 MS + 4 AC	- Any other MS or AC

-> *Participation in the IS may vary, not limited to the pS*

-> *Switzerland ?*

Main features in Article 185 decisions - Bodies

Initiatives	Implementation Structure	Decision-making body	Executive body	Advisory Bodies
AAL 2	Ambient Assisted Living AISBL (AALA) *	General Assembly **	Executive Board	Advisory Board
EDCTP2	EDCTP 2 - Implementation Structure (EDCTP 2 - IS)	General Assembly **	Secretariat (supervised by Management Board)	Scientific Advisory Committee
EMPIR	EURAMET e.V. *	EMPIR Committee ** (under the authority of EURAMET General Assembly)	Chairperson of the EMPIR Committee	Research Council
Eurostars 2	Eureka Secretariat (ESE) *	Eurostars 2 high-level group **	Head of ESE	Eurostars 2 Advisory Group (EAG) **

* AALA, EURAMET, ESE: non-profit associations with legal personality established under BE, DE, BE law respectively

** EC has observer status in the meetings of these bodies

Main specificities in Article 185 decisions (other than derogations)

- ❖ AAL 2:
 - ❖ Decentralised initiative, national grants
- ❖ EDCTP 2:
 - ❖ Includes activities not funded by the EDCTP IS, as contribution from the pS
 - ❖ Cooperation with sub-Saharan African countries
- ❖ EMPIR:
 - ❖ National Metrology Institutes ("NMIs") and Designated Institutes ("DIs")
- ❖ Eurostars 2:
 - ❖ Decentralised initiative, national grants
 - ❖ Definition of SMEs in line with recommendation 2003/361/EC
 - ❖ Definition of "R&D performing SMEs", one of four conditions must be met:
 - ❖ (a) reinvests at least 10 % of its turnover to research and development activities;
 - ❖ (b) dedicates at least 10 % of its full-time equivalents to research and development activities;
 - ❖ (c) has at least five full-time equivalents (for SME with no more than 100 full-time equivalents) for research and development activities; or
 - ❖ (d) has 10 full-time equivalents (for SME with over 100 full-time equivalents) for research and development activities.

AAL 2 decision: Derogations from RfP

(Decision 554/2014)



Article 5:

2. By way of derogation from Article 15(9) RfP **the financial capacity** of applicants **shall be verified by the designated national programme management** organisation in accordance with the rules of participation in the designated national programmes.
3. By way of derogation from Article 18(2) RfP **the grant agreements with participants shall be signed by the designated national programme management** agency.
4. By way of derogation from Article 23(1), (5) to (7), and Articles 25 to 35 RfP, **the funding rules of the designated national programmes apply** to the grants administered by the designated national programme management agencies.
5. By way of derogation from Articles 41 to 49 RfP, **the rules of the designated national programmes governing results, access rights to background and results apply**, without prejudice to the principle of open access to scientific publications set out in Article 18 RfP.

EDCTP 2 decision: Derogations from RfP (Decision 556/2014)



Article 6:

2. By way of derogation from Article 9(1)(b) RfP the **minimum number of participants** shall be **two legal entities established in two different Participating States** and a **third legal entity in a sub-Saharan African country listed in the EDCTP 2 annual work plan**.
3. By way of derogation from Article 10(1)(c) RfP **any legal entity established in a sub-Saharan country listed in the EDCTP 2 annual work plan shall be eligible for funding**.
4. ... the EDCTP 2 - IS may launch **joint calls** with third countries or their scientific and technological organisations and agencies, with international organisations **or with other third parties, in particular non-governmental organisations**, in accordance with the rules developed based on Article 12 RfP.

EMPIR decision: Derogations from RfP (Decision 555/2014)



Article 5:

2. By way of derogation from Article 29(1) RfP, **indirect eligible costs** of NMIs and DIs participating in projects funded by EMPIR shall be determined by applying a **flat rate of 5%** of their total direct eligible costs, excluding direct eligible costs for subcontracting and the costs of resources made available by third parties which are not used on the premises of the beneficiary, as well as financial support to third parties.

3. & 4. The interim evaluation of EMPIR ... shall include an assessment of the full indirect costs of the NMIs and the DIs participating in EMPIR projects and of the corresponding institutional funding.

On the basis of this assessment and for the purpose of Article 2(2), **EURAMET may adapt the flat rate** set out in paragraph 2 of this Article.

5. **If insufficient, EURAMET may**, by way of derogation from Article 28(3) RfP **apply a lower reimbursement rate to the eligible costs of the NMIs and the DIs** participating in projects funded by EMPIR.

Eurostars 2 decision: Derogations from RfP (Decision 553/2014)

Article 8:



2. By way of derogation from Article 15(9) RfP **the NFBs, under the coordination of the ESE, shall verify the financial capacity of all applicants** for funding under Eurostars 2.
3. By way of derogation from Article 18(2) RfP, **grant agreements** with beneficiaries of indirect actions under Eurostars 2 **shall be signed by the NFBs concerned**.
4. By way of derogation from Article 23 (1), (5), (6), and (7), and Articles 28 to 34 RfP, the **funding rules of the participating national programmes** shall apply to Eurostars 2 grants administered by the NFBs.

-> **No derogation from IPR rules**

List of derived (from the general H2020 MGA) MGAs for Art. 185 initiatives

Article 18(1) RfP: The Commission shall, in close cooperation with the Member States, draw up model grant agreements between the Commission or the relevant funding body and the participants ...

-> No EC role in drawing up MGAs in AAL 2 and in Eurostars 2

	Funding Body	Derived Model Grant Agreement(s) (MGAs)
1	EDCTP Association	EDCTP 2 mono-beneficiary MGA
2		EDCTP 2 mono-beneficiary MGA with options for fellowships
3		EDCTP 2 multi-beneficiary MGA
4	EURAMET	EMPIR mono-beneficiary MGA
5		EMPIR multi-beneficiary MGA

-> Contain common specificities

-> Additional, individual specificities exist

Main common specificities in Article 185 Initiatives MGAs

(multi-beneficiary) (compared to the general H2020 MGA) falling under the scope of Art. 18(1) RfP

- **The legal entity signing the GA** is not the EU represented by the EC but **the IS** => replacement of the "EU" by the IS or addition of the IS when rights are concerned. JRC=normal beneficiary
- **Terminology**, e.g. work programme->**work plan**; EU funding -> "EDCTP 2/EMPIR funding"
- The **IS does not use the EC electronic exchange system** or own system allowing electronic signature, which affects e.g. communication between parties; signature of GA and of amendments, submission of the reports: Art. 17.2, 41.2, 52, 55.2, 56, 58 + New Annex 7 for periodic technical report
- **Commission responsible for approval of certificate on the methodology**, but submitted to the IS: Art. 18.1.2
- **Absence of PGF**: Removal of the reference to the PGF as regards the amount retained for the PGF: Art. 21.2, the release of the amount retained for the PGF: Art. 21.4, when calculated the amount to be recovered: Art. 44.1, intervention of the PGF: Art. 44.1.2, 44.1.3, 50.2.2
- Right to carry out **checks, reviews and audits** for the IS and the EC: Art. 22.1
- **Removal of the possibility to apply the extension of findings from another grants** in respect to: consequences of findings in checks, reviews, audits and investigations: Art. 22.5.2, 22.5.3; rejection of costs: Art. 42.1.2, suspension of payments: Art. 48.1, suspension of the implementation of the action: Art. 49.2.1, calculation the debt of the beneficiary in case of the termination of its participation: Art. 50.3.1
- **Removal of the option of specific institutional access rights** for calls under the specific objective on "secure societies" cf. Art. 49 RfP: Art. 31.5
- **Removal of paragraph on Commission making available information on results to other institutions** cf. Art. 4 RfP: Art. 36.1
- New provision regarding the **processing of the personal data** by the IS: EDCTP Association and Euramet are private law entities established in a MS and must comply with the national law on data protection: Art. 39.1
- **Removal of reference to enforceable decisions** under Art. 299 TFEU: Art. 44.1, 45.3, 46.2, 57.2
- **Competent Belgian national court (not EU courts) has jurisdiction. Competence for "offsetting" disputes + option for jurisdiction** for the Dutch (EDCTP 2)/German (EMPIR) national court: Art. 57.2

Main individual specificities in the EDCTP2 (multi beneficiary) MGA (compared to the general H2020 MGA)



Provision	Content
7.1	General obligation to properly implement the action: addition of the obligation to comply with the standards on good clinical practice adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH GCP Guidelines")
20.3, 21, 44.1.2, 50.2.2, 50.3.3	Beyond the general H2020 MGAs approach for payments to the coordinator, payments can also be made (option) directly to beneficiaries * (see also EMPiR, where this is the only approach)
21.2	Option on the request of a pre-financing guarantee from one or several beneficiaries *
21.3	Calculation of the amount due as interim payment by the EDCTP 2 Association in the following steps: (...) Revised Step 2: Limit to [OPTION by default: 90%] [OPTION to be used by the EDCTP Association in exceptional cases and following an assessment of the financial risk and the technical implementation of the action: [...]%] of the maximum grant amount *
44.1.2	Recovery at the payment of the balance: New mean of recovery : drawing on the pre-financing guarantee (if the option is activated) *

* related to the protection of the EU financial interests in the absence of the PGF



European
Commission

Main individual specificities in the EMPIR (multi beneficiary) MGA (compared to the general H2020 MGA)



Provision	Content
Preamble	Options for distinguishing the coordinator and the beneficiaries who are "NMI" or "DI" (from PS) from other beneficiaries
6.2.E(a)	Flat rate for indirect costs for NMIs and DIs is 5%
20.2.	Only two reporting periods (operational specificity of the EMPIR projects)
20.2.a, 20.2.b	New options regarding the request for the payment of the second and the third pre-financing payment . Linked to options under Article 21.1 and to Annex 4(a) on the use of the previous pre-financing payment *
20.3	Periodic report includes the method for allocating the amount to be paid to each beneficiary **
21.1, 21.7	Payments are only made directly to the beneficiaries and options are introduced to allow for the possibility to pay the pre-financing in two or three payments *
21.2	Options regarding the possibility to pay the pre-financing in two or three payments * & Option allowing to request a pre-financing guarantee instead of two or three payments for the beneficiary other than NMIs and DIs *
21.3	Interim payments are limited to 85% of the maximum grant amount *
21.8	Bank accounts of each beneficiary (necessary in principle only for those receiving the EMPIR funds) **
41.2	Internal division of roles and responsibilities, the role of coordinator: it does not include the distribution of funds **
44.1.1	Recovery after the termination of a beneficiary's participation: Not applicable *
44.1.2	Recovery at the payment of the balance (44.1.2) **: <ul style="list-style-type: none"> - obligation to inform all the beneficiaries: pre-information letter - the coordinator submits observations on behalf of all the beneficiaries - confirmation of recovery must also be sent to all the beneficiaries New means of recovery: <ol style="list-style-type: none"> 1. for the beneficiaries other than NMIs and DIs by drawing on the pre-financing guarantee (if the option is activated) 2. for a beneficiary NMI or DI, by holding the other NMIs and DIs jointly and several liable, up to the maximum EMPIR contribution indicated in the estimated budget (as last amended)
44.1.3	Recovery after the payment of the balance (44.1.3) **: New mean of recovery: Same as point 2. above.
Annex 4a	Model for the statement on the use of the previous pre-financing payment: option to be used in case of two or three pre-financing payments foreseen in Article 20.2 *

* related to the protection of the EU financial interest in the absence of the PGF

** consequence of direct payment to beneficiaries

Overview of payment arrangements

Payment arrangement	H2020 MGA	EDCTP 2 MGA	EMPIR MGA
Pre-financing payment	ONE 5% retention of the PGF	ONE	ONE or Splitting of the pre-financing into 2 or 3 payments
Possibility to request pre-financing guarantee	NO	YES (option)	YES for beneficiaries other than the NMIs and DIs (option)
Interim payment(s)	YES with limit of 90% of the maximum grant amount	YES with limit of 90% (option by default) of the maximum grant amount or other %	YES with limit of 85% of the maximum grant amount
Payment of the balance	YES	YES	YES
Payments made via coordinator	YES	YES (option)	NO
Payments made directly to beneficiaries	NO	YES (option)	YES

Overview of financial guarantees

Guarantee	H2020 MGA	EDCTP 2 MGA	EMPIR MGA
PGF	YES	NO	NO
Possibility to request pre-financing guarantee	NO	YES	YES for beneficiaries other than the NMIs and DIs (option)
Joint and several financial liability from a linked third party	YES (option)	YES (option)	YES (option)
Joint and several financial liability between beneficiaries	NO	NO	YES, only between NMIs and DIs

Overview of means of recovery by phase

Mean of recovery	H2020 MGA	EDCTP 2 MGA	EMPIR MGA
1. After termination of a beneficiary's participation			
Offsetting, Holding the linked third party liable, Taking legal action or Adopting an enforceable decision	YES on behalf of the PGF	Not Applicable	Not Applicable
2. At payment of the balance			
Offsetting	YES	YES	YES
Drawing on the PGF	YES	Not Applicable	Not Applicable
Holding the linked third party liable - if requested (option)	YES on behalf of the PGF	YES	YES
Holding the other beneficiaries liable	NO	NO	YES, only between NMIs and DIS
Drawing on the pre-financing guarantee - if requested (option)	NO	YES	YES
Taking legal action	YES on behalf of the PGF	YES	YES
Adopting an enforceable decision	YES on behalf of the PGF	Not Applicable	Not Applicable
3. After the payment of the balance			
Offsetting	YES	YES	YES
Drawing on the PGF	YES	Not Applicable	Not Applicable
Holding the linked third party liable - if requested (option)	YES on behalf of the PGF	YES	YES
Holding the other beneficiaries liable	NO	NO	YES, only between NMIs and DIS
Taking legal action	YES on behalf of the PGF	YES	YES
Adopting an enforceable decision	YES on behalf of the PGF	Not Applicable	Not Applicable

❖ Amendment of the general H2020 MGA

- ❖ Followed by new versions of derived MGAs for Article 185 Initiatives

❖ Evaluation of Article 185 Initiatives

- ❖ Interim evaluation of the Initiatives

✓By 30 June 2017

➤ **Article 185 initiatives (Art. 185 TFEU) in Horizon 2020:**

http://ec.europa.eu/research/era/art-185_en.htm

<http://ec.europa.eu/programmes/horizon2020/en/area/partnerships-industry-and-member-states>